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CONTRACTING ORGANIZATION: Mayo Clinic
Rochester, MN 55905

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13. ABSTRACT (Maximum 200) There is a critical need for a small, portable device to provide ventilatory support to critically-ill battlefield casualties. The goal of this work is to develop a prototype ventilator suitable for incorporation into the LSTAT unit. This goal has been successfully met, with units delivered to and currently being tested by Northrop-Grumman, the prime contractor for the LSTAT project.			
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FOREWORD

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PI - Signature

12/16/97

Date

Table of Contents

Foreword.....	3
I. Introduction.....	5
II. Body.....	5
Task I. Initial Prototype Design.....	5-6
Task II. Prototype Development.....	6-8
III. Conclusions.....	8
IV. References.....	8
V. Appendices.....	A1 – A2
VI. Bibliography.....	8
VII. Personnel Funded.....	8

I. Introduction

There is a critical need for a small, portable device to provide ventilatory support to critically-ill battlefield casualties. No prior device is available which can operate independently of compressed gas sources and line power. The purpose of this project was to develop a prototype ventilator suitable for incorporation into the Life Support for Trauma and Transport (LSTAT) project.

The scope of this work has continued to evolve throughout the project period, as documented in the interim project reports. Originally, it was conceived to be essentially a feasibility study. However, early in the project period it became apparent that WRAIR desired an actual pre-production prototype for incorporation into a prototype LSTAT unit. To meet this goal, we modified the original grant (see attached letter to Dr. Satava explaining this modification, Attachment 1), including a subcontractor (Omni-Tech Medical, Inc.) recommended by WRAIR to actually fabricate the device. As part of the process, initial units were delivered to Northrop Grummon and incorporated into an initial prototype.

In early 1996, the scope of the proposal was further modified by WRAIR, tasking us to build several more prototypes for testing and evaluation of the LSTAT (referred to as the LSTAT '96 Testing and Evaluation Prototype). Our prototype was modified to meet the requirements of this activity, and the units were delivered to Northrop beginning in December of 1996. Documentation for FDA certification of these devices was also submitted. These units have undergone further testing and modification at the request of Northrop and WRAIR.

The original design goals of the device have undergone extensive modification throughout this process. The need for immediate FDA certification favored use of existing technologies when possible, discouraged experimentation with unproven technology, and postponed implementation of features such as automatic servo control of ventilation. However, we believe that we have successfully developed a hardware and software platform that will both provide good patient care in its current incarnation and serve as a research tool to continue development of further strategies for care of the critically-ill patient.

II. Body

Task I.--Initial Prototype Design

Task IA: Research and Design. A variety of approaches were considered. For reasons of flexibility and reliability, a high pressure/low flow design was chosen. After extensive research, a commercially-available air compressor was chosen to provide high-pressure gas, with modifications for appropriate handling of water vapor, heat dissipation, etc. An initial microprocessor-controlled pneumatic system was designed.

Other design issues were investigated at the request of WRAIR:

- 1) It was desired to include the capability to deliver volatile anesthetics through the ventilator system. However, extensive evaluation of existing technology revealed that no existing technology is suitable for the in-line administration of anesthetic vapors. Design of such a system is feasible but beyond the scope of this project. The most appropriate solution was felt to be to use the LSTAT ventilator to drive a separate portable anesthesia machine that could be manufactured as an attachment to the LSTAT sled. It was decided not to pursue this option at this time.
- 2) At one point in the design the use of fuzzy logic control systems were considered for provision of ventilator control. As part of these considerations, the PI at the suggestion of WRAIR visited the Applied Research Laboratory at Penn State to explore this option. However, as the emphasis on the immediate production of the '96 LSTAT T&E article developed, it was decided by WRAIR not to pursue this approach. Other approaches for servo control have been implemented (see below).

Task IB: Initial Prototype Fabrication. This initial design was fabricated and an initial unit delivered to Northrop for incorporation into the first version of the LSTAT.

Task II.--Prototype Development

The initial prototype was modified extensively during the design process. Highlights included:

- Adoption of distributed design of ventilator components (i.e., throughout the LSTAT sled)
- Addition of inspiratory hold capability, involving incorporation of a separate pneumatic valve to control the state of the exhalation valve;
- Incorporation of servo-controlled valve in inspiratory limb to permit regulation of inspiratory flow and tidal volume;
- Further modification of the air compressor, including servo control of motor speed to conserve power;
- Redesign of control board to allow for additional sensor inputs;
- Integration of sensors (airway CO₂, pulse oximetry, airway gas flow, airway pressure), including waveform display;
- Design and testing of air/oxygen proportioning device;
- Engineering of operator interface and display according to Northrop and WRAIR requirements;
- Communication and data logging protocols with the LSTAT sled.

The ventilator that has resulted from this process can be described as an electronic single circuit, volume-constant, time-cycled, variable flow ventilator. It utilizes high pressure gas with high internal resistance to control pressure. Tidal volume can be set from 200 ml to 1200 ml and is servo-controlled. The ventilation time cycle and phases (inspiration/expiration) are controlled with a breaths per minute switch and an I:E ratio switch. Inspiratory pressure hold is provided,

variable from 0 to 30% of inspiration time. The ventilator provides the capability to supply an air/oxygen blend to the patient ranging from 21% to 100% O₂. Four primary ventilation modes are available, including standby, intermittent mandatory ventilation, assist, and manual breaths. A graphics electroluminescent display panel presents ventilation performance and physiological data to the operator. In addition to instantaneous airway pressure and peak airway pressure, the ventilatory measures and displays tidal volume, end-tidal carbon dioxide, oxygen saturation, and heart rate. Instantaneous CO₂, pressure and flow wave forms can also be displayed. The display panel also displays messages and prompts that guide the operator in the effective use of the ventilator. A matrix touchscreen is overlaid on the EL display. The touchscreen provides areas to set ventilation control parameters and to switch ventilator display modes.

We were further tasked by WRAIR to produce 7 of these units for the '96 LSTAT T&E articles, which was done. We also delivered appropriate documentation for 510(k) FDA approval of the device, and assisted Northrop with the FDA approval process for the LSTAT platform (including the ventilator). These devices were tested at the manufacturer, in our laboratory at Mayo, and at Northrop (results available on request). These tests show that the ventilator operates within specifications.

As mentioned above, the emphasis on immediate production of a working device suitable for FDA approval and human testing decreased effort towards development of advanced servo algorithms for truly "automatic" operation of the ventilator. However, after completion of work on the ventilators for the '96 LSTAT T&E articles, an initial algorithm was implemented on a ventilator at Mayo, the primary goal being simplicity and reliability. The primary limitation of any such algorithm is the reliability of sensed parameters, which may be uncertain under transport conditions. We determined that the most reliable parameter is the airway pressure. Our algorithm thus first uses a target plateau airway pressure to guide increases in tidal volume according to protocol. Once this target is achieved, the end-tidal carbon dioxide is checked (if available), and further adjustments in minute ventilation are made. This approach should provide at least minimal ventilatory support during transport until adjustments can be made by medical personnel. The algorithm has been successfully tested in bench trials.

The original proposal called for animal testing of the final prototype. However, in discussions with WRAIR, it has been decided that animal testing may be best accomplished at WRAIR, where the entire LSTAT platform (including the ventilator) can be evaluated. Thus, evaluation of the ventilator has been confined to bench testing using artificial lungs, as all phases of ventilator operation can be evaluated in this manner. The primary use of animal testing will be in the interaction of several systems during normal conditions and models of shock.

A complete description of ventilator operation, including specifications, is given in the attached 'Operator's Manual' (Attachment 2). Complete design information, including full schematics and working drawings, is available upon request.

Further development of the ventilator is possible if desired, as outlined in the Optional Tasks 3 and 4 in the modified proposal. Developmental goals would include

- Full evaluation of ergonomic factors associated with ventilator operation, with subsequent modification of its operation as appropriate;
- Further reductions in size, weight, and power requirements of the device;
- Refinement of automatic servo-control algorithm;
- Integration of ventilator control with other systems on the LSTAT (e.g., infusion pumps) based on new algorithms for shock/trauma management.

III. Conclusion

We have successfully designed and constructed a ventilator for use in the LSTAT that is currently undergoing testing and the FDA approval process.

IV. References - none

V. Appendices (see attached)

Attachment 1 - Letter to COL Satava describing the grant modification.

Attachment 2 - Operators manual, including description and specifications.

VI Bibliography - none

VII. Personnel Funded -

David O. Warner, M.D. - Principal Investigator

Darrell Loeffler - Research Technician

September 20, 1994

Dr. Richard Satava
ARPA/MTD
Advanced Research Projects Agency
3701 North Fairfax Drive
Arlington, VA 22203-1714

Dear Doctor Satava:

Enclosed is a draft of a revision to the proposal entitled "Development of a Portable Microventilator". As we have discussed, it has become evident that our original proposal will not meet the current needs of the LSTAT ventilator as defined by Walter Reed Army Institute of Research (WRAIR), Department of Combat Trauma, Division of Surgery. The original proposal was for a simple design suitable for stabilization and transport. Current specifications describe a versatile device that will be used not only for stabilization and transport, but to meet the needs for mechanical ventilation throughout the perioperative period, including the delivery of anesthetic gases. To meet WRAIR specifications, a considerably more sophisticated approach is required. In addition, the original proposal was not designed to meet the desired timetable (basic design completed by April 1997). The aim of this original proposal was only to determine the feasibility of a concept, using a bench prototype, within this timeframe; it is now required that a finished prototype that meets the size and weight requirements of the LSTAT be developed by this time. This was described as an optional future task in the original submission. In short, the needs of the LSTAT program and WRAIR have evolved considerably since the submission of the original proposal, requiring a considerable expansion in the scope of the project.

We have initiated discussions with Omni-Tech Medical of Topeka, KS, a company with considerable experience in the design and production of small ventilators. We have also conferred with the personnel at WRAIR who have been actively involved in the development of this device. Based on these interactions, we have developed a revised proposal that we believe can meet the needs of the project, representing a collaborative effort between Mayo and Omni-Tech, with assistance from WRAIR. The aim of this proposal is to deliver a prototype that will meet the basic needs of the LSTAT project by the fall of 1996 (work described in Tasks 1 and 2). Optional tasks (tasks 3 and 4), requiring an additional 24 months of development, would concentrate on adding advanced capabilities, such as measurement of oxygen consumption, that are currently not feasible, but are highly desired by WRAIR personnel, and represent cutting-edge technology yet to be developed. In essence, we are skipping over the feasibility studies described in the first two years of the original proposal, and proceeding directly to development of a pre-production prototype. This revised proposal has several major advantages over the original:

- 1) The revised proposal aims to meet the specifications promulgated by WRAIR subsequent to the time of submission of the original proposal. The basic design described in the original proposal cannot meet these requirements.

- 2) The original proposal was limited to a feasibility study, whereas the revised proposal aims to produce an actual working prototype that meets LSTAT size and weight requirements.
- 3) The assistance from WRAIR should ensure that the ventilator will indeed meet military requirements, and will allow continuous input by military staff. Furthermore, the contacts afforded by WRAIR with technology vendors has and will continue to greatly benefit the design process.
- 4) The inclusion of industry collaboration from the outset (not envisioned in the original proposal until much later in the design process) will allow proper documentation and procedures required by the FDA and other regulatory bodies that will speed eventual approval of the device for clinical use. Recent military experience with small ventilators demonstrates that this consideration is especially important. Proper observance of these procedures will also speed technology transfer to the civilian sector. Furthermore, factors such as reliability and engineering for environmental constraints will now be considered as an integral part of the design process.
- 5) Plans for technology to be developed by other ARPA contractors regarding oxygen production and the measurement of respiratory gasses are now incorporated as an integral part of the design process.

Expansion of the scope of the project will also require an expansion of the resources required for its successful completion. We have prepared what we believe to be a reasonable preliminary estimate of the costs involved to complete the first 2 tasks (covering the first 2 years of development), totalling approximately \$900,000. Under this arrangement, Mayo would serve as the prime contractor, with Omni-Tech serving as a subcontractor. Details of the arrangement are found in the body of the revised proposal. Please let me know if funding in this range would be feasible. I again want to emphasize that although the total amount exceeds that originally proposed, so too does the scope and ambition of the proposed work.

We are prepared to proceed with signing the current version of the contract forwarded to us by the contracts officer to perform the work described in the original proposal, so as to access the funds allocated for this fiscal year, with the recognition that modification of the contract will be necessary to meet your needs.

I remain excited about commencing work on this project, and am more optimistic than ever that the device can be built by the team we are assembling. I remain committed to developing a ventilator that will not only meet your basic needs, but push the envelope of the possible.

Sincerely,

David O. Warner, M.D.

MAYO CLINIC LSTAT Ventilator

Operator's Manual

ALLIED HEALTHCARE PRODUCTS, inc..
K.V.A. PRODUCT DEVELOPMENT GROUP, llc.
MAYO CLINIC

11-18-96

REV: A 9/97

CONTENTS

<u>SECTION</u>	<u>PAGE</u>
1. GENERAL DESCRIPTION	1
2. WARNINGS, CAUTIONS AND NOTES	2
2.1 DEFINITIONS	2
2.2 SUMMARY OF WARNINGS AND CAUTIONS	2
3. PERFORMANCE SPECIFICATION	5
4. VENTILATOR CONTROLS	7
4.1 CONTROL PANEL	7
4.2 GRAPHICS DISPLAY AND MATRIX TOUCHSCREEN	10
4.3 CHANGING PARAMETERS	13
4.4 AUTOMATIC MODE OF OPERATION	14
5. VENTILATOR ALARMS	16
5.1 ALARM CONDITIONS	16
5.2 ALARM MESSAGES	17
5.3 AUDIBLE ALARM CONTROL	17
5.4 VENTILATOR HARDWARE FAULT CODES	18
6. VENTILATOR NOTICES	19
6.1 FOREWARNING NOTICES	19
6.2 GENERAL INFORMATION NOTICES	19
7. VENTILATOR CONNECTIONS	21
7.1 PATIENT TUBING CIRCUIT	21
7.2 SENSORS	21
7.3 AIR SOURCE CONNECTION	24
7.4 OXYGEN SOURCE CONNECTION	24
7.5 PRESSURE SENSE CONNECTIONS	24
7.6 ELECTRIC CONNECTIONS	25
8. CARE AND MAINTENANCE	26
8.1 CLEANING	26
8.2 MAINTENANCE	27
8.3 REPAIR	27
8.4 STORAGE	27

LIST OF FIGURES

FIGURE 1. CONTROL PANEL
FIGURE 2a. NORMAL SCREEN - STANDBY
FIGURE 2b. NORMAL SCREEN - ON
FIGURE 3a. CHANGE SCREEN 1
FIGURE 3b. CHANGE SCREEN 2
FIGURE 4. WAVEFORM SELECT SCREEN
FIGURE 5a. CO2 WAVEFORM DISPLAY SCREEN
FIGURE 5b. FLOW WAVEFORM DISPLAY SCREEN
FIGURE 6. LOWPOWER SCREEN
FIGURE 7a. PNEUMATIC CONNECTIONS
FIGURE 7b. ELECTRIC CONNECTIONS

1. GENERAL DESCRIPTION

The LSTAT Ventilator is an electronic single circuit, volume-constant, time-cycled, variable flow ventilator. It utilizes high pressure gas with high internal resistance to control pressure. It is a non-constant pressure generator and it produces a constant flow pattern (inspiratory square wave). Tidal Volume (V_T) can be set from 200 ml to 1200 ml. The ventilation time cycle and phases (inspiration/expiration) are controlled with a Breaths per Minute (BPM) switch and an I:E Ratio switch. Inspiratory pressure hold is provided and hold time can be varied from 0 to 30% (in 10% steps) of inspiration time. The LSTAT Ventilator also provides the capability to supply an air/oxygen blend to the patient ranging from 21% to 100% O_2 in 5% steps

The LSTAT Ventilator has four primary ventilation modes:

1. **STBY** - standby. No controlled ventilation occurs.
2. **IMV** - intermittent mandatory ventilation. When this mode is selected, controlled ventilation occurs at the set BPM and I:E Ratio with no assisted breaths.
3. **ASSIST** - assist control ventilation. Controlled ventilation occurs at the set BPM and I:E Ratio with assisted breaths delivered whenever the patient attempts to breath. Assisted breath negative pressure sensitivity can be set from -2 cmH_2O to -10 cmH_2O (below the end expiratory pressure) with 2 cmH_2O resolution.
4. **MANUAL BREATH** - manually initiated ventilation. A single breath is delivered whenever the MANUAL BREATH button is depressed.

In addition, the LSTAT Ventilator for the Mayo Clinic provides an automatic mode of ventilation that alters ventilation parameters based on patient response and target control parameters set by the operator. The control parameters are:

1. **TARGET PEAK AIRWAY PRESSURE**. The LSTAT Ventilator automatically adjusts flow to achieve a target peak airway pressure reading set by the operator.
2. **MAXIMUM $EtCO_2$** . The LSTAT Ventilator automatically increases BPM if the $EtCO_2$ reading exceeds an adjustable maximum $EtCO_2$ set by the operator. The rate of the BPM increase is adjustable. The step increase in BPM can be varied from 1 to 5 BPM, and the sampling time for step increases can be varied from 1 to 5 minutes. When the $EtCO_2$ reading is less than the maximum setting, the BPM is held constant.

A graphics Electroluminescent (EL) display panel presents ventilation performance and physiological data to the operator. In addition to instantaneous airway pressure (AP) and peak airway pressure (PAP), the LSTAT Ventilator measures and displays V_T , End tidal CO_2 ($EtCO_2$), oxygen saturation (SpO_2) and heart rate. Instantaneous CO_2 , pressure and flow waveforms can also be displayed. The EL display panel also displays messages and prompts that guide the operator in the effective use of the ventilator. A matrix touchscreen panel is overlaid on the EL display. The touchscreen provides "Touch Buttons" to set ventilation control parameters and to switch Ventilator display modes.

2. WARNINGS, CAUTIONS AND NOTES

Warning, caution and note statements, in this document, identify special conditions or practices that the operator must be aware of.

2.1 DEFINITIONS

WARNING - IDENTIFIES CONDITIONS OR PRACTICES THAT COULD RESULT IN PERSONAL INJURY.

CAUTION - IDENTIFIES CONDITIONS OR PRACTICES THAT COULD RESULT IN DAMAGE TO THE VENTILATOR OR OTHER EQUIPMENT.

NOTE - identifies important information for the most effective use of the ventilator.

2.2 SUMMARY OF WARNINGS AND CAUTIONS

WARNING: THE LSTAT VENTILATOR IS NOT FDA CERTIFIED.

WARNING: PATIENTS REQUIRING LIFE SUPPORT EQUIPMENT MUST ALWAYS BE UNDER THE CONSTANT MONITORING OF MEDICAL PRACTITIONERS FAMILIAR WITH THE LSTAT VENTILATOR OPERATION. THERE IS ALWAYS THE POSSIBILITY OF SITUATIONS REQUIRING IMMEDIATE CORRECTIVE ACTION.

WARNING: ONLY QUALIFIED PERSONNEL, TRAINED IN THE USE OF VENTILATORS SHOULD OPERATE THIS VENTILATOR.

WARNING: THE OPERATOR SHOULD ALWAYS INSURE THE CORRECT CONNECTION OF THE PATIENT CIRCUIT AND THAT ALL TUBES ARE FREE OF OBSTRUCTIONS. NO AMOUNT OF AUTOMATED MONITORING CAN OBIVATE THE NEED FOR AN OPERATOR'S CLINICAL SURVEILLANCE.

WARNING: THE LSTAT VENTILATOR DEFAULT SETTINGS ARE NOT INTENDED FOR LONG TERM VENTILATOR SUPPORT. THE FACTORY SET DEFAULT SETTINGS MAY BE VERY DIFFERENT FROM WHAT IS REQUIRED FOR EACH INDIVIDUAL CLINICAL SITUATION.

WARNING: ALWAYS DISCONNECT THE PATIENT CIRCUIT BEFORE TURNING ON POWER.

WARNING: ALWAYS VERIFY CORRECT OPERATION BEFORE CONNECTING TO PATIENT.

WARNING: THE BIRD#999-2576 EXHALATION VALVE MUST BE USED. OTHER EXHALATION VALVES WILL NOT FUNCTION PROPERLY.

WARNING: THE EXTERNAL AIR SOURCE MUST BE REGULATED TO AT LEAST 30 PSI AND NO GREATER THAN 60 PSI.

WARNING: THE EXTERNAL O2 SOURCE MUST BE REGULATED TO AT LEAST 30 PSI AND NO GREATER THAN 60 PSI.

WARNING: IF THE SELFTEST FAILS, DO NOT ATTEMPT TO USE THE VENTILATOR.

WARNING: SET THE VENTILATION CONTROL PARAMETERS (BPM, I:E RATIO, V_T , AND $\%O_2$) TO THE DESIRED POSITION BEFORE STARTING VENTILATION.

WARNING: IF ASSIST MODE IS SELECTED, MONITOR PERFORMANCE TO INSURE AUTO-CYCLING (UNINTENTIONAL ASSISTED BREATHS) DOES NOT OCCUR.

- WARNING:** THE FLOW SENSOR MUST BE ATTACHED FOR ACCURATE V_T READINGS.
- WARNING:** THE VENTILATOR MUST BE POWERED (I.E. THE MODE MUST NOT BE OFF) FOR THE MANUAL BREATH MODE TO FUNCTION.
- WARNING:** $E_T\text{CO}_2$ LOW LIMIT MUST BE SET TO ALARM ON NO OR LOW $E_T\text{CO}_2$.
- WARNING:** SpO_2 LOW LIMIT MUST BE SET TO ALARM ON NO OR LOW SpO_2 .
- WARNING:** LARGE INCREASES OR DECREASES IN V_T WILL RESULT IF THE BPM OR I:E RATIO SETTINGS ARE DRASTICALLY CHANGED.
- WARNING:** P_{MAX} LIMIT AND P_{MAX} TARGET MUST BE SET TO INSURE VITAL CAPACITY IS NOT EXCEEDED IN AUTOMATIC MODE.
- WARNING:** OPERATING THE VENTILATOR WITH THE "VENTILATOR HARDWARE FAULT ALARM" ACTIVE COULD RESULT IN PERSONAL INJURY.
- WARNING:** IF P_{MIN} IS SET TO 0 CMH₂O, LEAKS WILL NOT BE DETECTED.
- WARNING:** TURNING OFF AUDIBLE ALARMS COULD RESULT IN PERSONAL INJURY.
- WARNING:** THE OXYGEN IN USE MESSAGE ONLY REFERS TO THE %O₂ SWITCH ON THE CONTROL PANEL. IT IS UP TO THE OPERATOR TO INSURE THE OXYGEN VALVE (REFER TO SECTION 7.4) IS SET CORRECTLY AND TURNED OFF WHEN NOT IN USE.
- WARNING:** ENSURE THE INTEGRITY OF THE PATIENT CIRCUIT AFTER INSTALLING THE FLOW SENSOR.
- WARNING:** DO NOT REUSE THE FLOW SENSOR. STERILIZATION MAY COMPROMISE PERFORMANCE.
- WARNING:** ENSURE THE INTEGRITY OF THE PATIENT CIRCUIT AFTER INSTALLING THE CO₂ SENSOR AIRWAY ADAPTER.
- WARNING:** DO NOT REUSE THE CO₂ AIRWAY ADAPTER. STERILIZATION MAY COMPROMISE PERFORMANCE.
- WARNING:** THE CO₂ SENSOR MUST BE CALIBRATED WHEN FIRST INSTALLED.
- WARNING:** IF CO₂ IS PRESENT DURING AN ADAPTER ZERO, CO₂ READINGS WILL BE ERRONEOUS.
- WARNING:** USE CAUTION WHEN USING OXYGEN, IT IS EXTREMELY VOLATILE.
- WARNING:** ENSURE THE OXYGEN VALVE IS OFF WHEN NOT IN USE.
- WARNING:** VERIFY THE VENTILATOR FUNCTIONS AFTER INSPECTING AND REPLACING FILTERS.

CAUTION: THE NOVAMETRIX CAPNOSTAT (CATALOG NO. 7167) CO₂ SENSOR MUST BE USED. OTHER CO₂ SENSORS WILL NOT FUNCTION PROPERLY AND WILL DAMAGE THE VENTILATOR.

CAUTION: THE NOVAMETRIX VENTRAK (CATALOG NO. 7222) FLOW SENSOR MUST BE USED. OTHER FLOW SENSORS WILL NOT FUNCTION PROPERLY AND WILL DAMAGE THE VENTILATOR.

CAUTION: THE NOVAMETRIX OXYSNAP (CATALOG NO. 8744) FINGER SENSOR MUST BE USED. OTHER SPO₂ SENSORS WILL NOT FUNCTION PROPERLY AND WILL DAMAGE THE VENTILATOR.

CAUTION: AIRWAY PRESSURE ABOVE 250 CMH₂O OR BELOW -200 CMH₂O WILL DAMAGE THE VENTILATOR.

CAUTION: THE PNEUMATIC CONNECTIONS MUST BE COVERED DURING CLEANING.

CAUTION: DO NOT USE THE FOLLOWING CLEANING AGENTS:

1. Butyl Alcohol
2. Denatured Ethanol
3. Freon
4. Chlorine Bleach Solution
5. Isopropyl Alcohol
6. Trichloroethane, Trichloroethylene
7. Acetone
8. Vesphene II
9. Enviroquat
10. Staphene
11. Misty.

CAUTION: THE PRESSURE SENSE TUBES (BLUE AND RED) MUST BE CONNECTED CORRECTLY TO THE CONTROL DISPLAY MODULE. THE BLUE TUBE IS CONNECTED TO THE PNEUMATIC CONNECTION LABELED WITH THE BLUE DOT. LIKEWISE, THE RED TUBE MUST BE CONNECTED TO THE PNEUMATIC CONNECTION LABELED WITH THE RED DOT. INCORRECT CONNECTION OF THESE TUBES WILL DAMAGE THE VENTILATOR.

3. PERFORMANCE SPECIFICATION

1. Gas Inputs	
1. External Medical Air Connection, Range:	30 to 60 psi
2. On-board Oxygen Connection, Range:	30 to 60 psi
3. Integral Compressed Air Source	Variable Speed, Piston Compressor, 55 psi
2. Tidal Volume Control, Range (Accuracy):	200 to 1200 ml ($\pm 3\%$ if Flow Sensor Connected, $\pm 12\%$ if Flow Sensor not Connected)
3. Flow Rate:	0 to 50 lpm
4. Primary Modes of Ventilation	Standby, IMV, Assist/Control, Manual Breath
5. Breaths per Minute, Range (Resolution):	5 to 28 (1 breath per minute)
6. I:E Ratio Setting, Range (Resolution):	2:1 to 1:5.5 (0.5)
7. Inspiratory Hold, Range (Resolution):	0 to 30% (10% of Insp. Time)
8. Assist Sense, Range (Resolution, Accuracy):	-2 cmH ₂ O to -10 cmH ₂ O (2 cmH ₂ O, ± 1 cmH ₂ O)
9. Air/O ₂ Blender, Range (Resolution, Accuracy)	21% to 100% O ₂ (5%, $\pm 7\%$)
10. Physiological/ Performance Numeric Displays	
1. PAP, Range (Resolution, Accuracy)	-10 to 80 cmH ₂ O (1 cmH ₂ O, ± 1 cmH ₂ O)
2. AP Gage, Range (Resolution, Accuracy)	-10 to 80 cmH ₂ O (1 cmH ₂ O, ± 1 cmH ₂ O)
3. V _T , Range (Resolution, Accuracy)	200 to 1200 ml (1 ml, $\pm 3\%$ of reading)
4. E _T CO ₂ , Range (Resolution, Accuracy)	0 to 100 mmHg (1 mmHg, ± 2 torr)
5. SpO ₂ , Range (Resolution, Accuracy)	80 to 100 % (1 %, $\pm 2\%$), 0-79% (1%, unspecified)
6. Heart Rate, Range (Resolution, Accuracy)	30 - 250 bpm (1 bpm, $\pm 1\%$ of full scale)
11. Physiological/ Performance Waveform Displays	
1. CO ₂ , Range (Resolution, cycles)	0 to 100 mmHg (5 mmHg, fixed 4 seconds)
2. AP, Range (Resolution, cycles)	-10 to 80 cmH ₂ O (5 cmH ₂ O, fixed 4 seconds)
3. Flow, Range (Resolution, cycles)	-10 to 80 l/min (5 l/min, fixed 4 seconds)
12. Adjustable Pressure Thresholds, Range (Resolution, Accuracy)	
1. Electronic Pressure Relief	5 to 80 cmH ₂ O (1 cmH ₂ O, ± 1 cmH ₂ O)
2. Minimum Pressure Threshold	0 to 80 cmH ₂ O (1 cmH ₂ O, ± 1 cmH ₂ O)
13. Audible and Visual Alarms	
1. Alarm Light	Red LED (Flashing, 2 Hz)
2. Alarm Message	Text Display on Graphics Display Module
3. Audible Annunciation	Continuous, Alternating Two Tones
14. Alarm Control	
1. Alarm Clear cleared	End Audible, Light and Message if alarm
2. Audible Disable	Disable Audible only.
3. E _T CO ₂ Disable	Disable E _T CO ₂ alarms only.
4. SpO ₂ Disable	Disable SpO ₂ alarms only.
15. Non-Adjustable Alarm Sources	
1. Inlet Air Pressure Drop, Threshold (Accuracy)	13 psi ($\pm .2$ psi)
2. Oxygen Pressure Drop, Threshold (Accuracy)	25 psi ($\pm .2$ psi)
3. E _T CO ₂ Sensor Fault	
4. Flow Sensor Fault	
5. SpO ₂ Sensor Fault	
6. Ventilator Controller Fault	
7. CO ₂ Sensor Calibration Required Alarm	
16. Adjustable Alarm Sources	
1. P _{MAX} , Range (Resolution, Accuracy)	5 to 80 cmH ₂ O (1 cmH ₂ O, ± 1 cmH ₂ O)
2. P _{MIN} , Range (Resolution, Accuracy)	0 to 75 cmH ₂ O (1 cmH ₂ O, ± 1 cmH ₂ O)
3. E _T CO ₂ Hi, Range (Resolution, Accuracy)	10 to 100 mmHg (1 mmHg, ± 2 torr)
4. E _T CO ₂ Lo, Range (Resolution, Accuracy)	0 to 100 mmHg (1 mmHg, ± 2 torr)
5. SpO ₂ Lo, Range (Resolution, Accuracy)	80 to 100 % (1 %, $\pm 2\%$)

17. Remote Monitoring via Bi-directional Asynchronous RS232 Port	
1. Setting	9600 BAUD, 8 data bits, 1 stop bit, no parity
2. Protocol	Continuous, , variable length data packets.
18. Remote Monitoring Parameters	
1. Alarm Status, Frequency	4 Hz
2. Mode Setting, Frequency	1 Hz
3. BPM Setting, Frequency	1 Hz
4. I:E Ratio Setting, Frequency	1 Hz
5. Tidal Volume Setting, Frequency	1 Hz
6. Insp. Hold Time Setting, Frequency	1 Hz
7. P _{MAX} Setting, Frequency	1 Hz
8. P _{MIN} Setting, Frequency	1 Hz
9. Assist Breath Setting, Frequency	1 Hz
10. Blender Setting, Frequency	1 Hz
11. SpO ₂ Level, Frequency	20 Hz
12. EtCO ₂ Level, Frequency	20 Hz
13. Instantaneous Flow, Frequency	20 Hz
14. Minute Volume, Frequency	20 Hz
15. Compressor ON/OFF, Frequency	1 Hz
16. Safe Valve ON/OFF, Frequency	1 Hz
19. Weight (excluding case and power supply)	20 lbs.
20. Power	
1. Compressor	24 VDC @ 3.7A max continuous, 8A max
2. Ventilator	5 VDC @ 2.5 A max., 12 VDC @ 1.9 A max., -12 VDC @ 0.3 A max.
21. Operating Temperature Range	
1. Ventilator (w/o Flow, EtCO ₂ , SpO ₂ , Blend. Comp.)	-25°C to +65°C
2. EtCO ₂ :	0°C to 60°C
3. SpO ₂ :	10°C to 40°C
4. Blender	0°C to 70°C
5. Compressor	10°C to +40°C
6. Flow Meter:	0°C to 50°C
22. Flow Meter Operating Gas Temperature, Range	0°C to 50°C
23. Storage Temperature Range	
1. Ventilator (w/o EtCO ₂ , SpO ₂ , Blender, Comp.)	-46°C to +85°C
2. EtCO ₂ :	-30°C to +65°C
3. SpO ₂ :	-20°C to +70°C
4. Blender	-40°C to +85°C
5. Compressor	-10°C to +70°C
6. Flow Meter:	-10°C to +70°C
24. Operating/Storage Relative Humidity Range	
1. Ventilator (without Flow, EtCO ₂ , SpO ₂ , Blender)	15 to 93% @ 40°C non-condensing
2. SpO ₂ :	15 to 90% @ 40°C non-condensing
3. EtCO ₂ :	15 to 95% @ 40°C non-condensing
4. Blender	30 to 75%
5. Flow Meter:	30 to 75%
25. Shock/Vibration	10g in 11ms half sine wave/ 50 to 500Hz; 5g 3 axis
26. Altitude	0 to 15,000 ft.
27. Automatic Mode of Operation Control Parameters	
1. Target PAP, range (resolution, accuracy)	1 to 79 cmH ₂ O (1 cmH ₂ O, ±1 cmH ₂ O)
2. Maximum EtCO ₂ (resolution, accuracy)	0 to 100 mmHg (1 mmHg, ±2 torr)
a. BPM Delta	1 to 5 BPM
b. Check Time Interval	1 to 5 Minutes

4. VENTILATOR CONTROLS

The LSTAT Ventilator is controlled by an integrated Control Panel and through a Matrix Touchscreen overlaid on the EL Graphics Display. The following paragraphs describe the operation of the LSTAT Ventilator controls.

4.1 CONTROL PANEL

The LSTAT Ventilator Control Panel provides the following controls (refer to Figure 1.) to set ventilation control modes and parameters:

- | | |
|-----------------------------|---|
| 1. MODE | 8 position, detent: OFF, STANDBY, IMV, ASSIST-2, ASSIST-4, ASSIST-6, ASSIST-8, ASSIST-10. |
| 2. TIDAL VOLUME (ml) | 21 position, detent: 200 to 1200 ml, in 50 ml steps |
| 3. I:E RATIO | 12 position, detent: 2:1 to 1:5.5, in 0.5 steps |
| 4. BPM | 24 position, detent: 5 to 28 BPM, in 1 BPM steps |
| 5. %O₂ | 17 position, detent: 21% to 100%, in 5% step |
| 6. ALARM MUTE | Momentary, Pushbutton (RED) |
| 7. MANUAL BREATH | Momentary, Pushbutton (GREEN) |
| 8. COMP | Locking Toggle Switch: ON, OFF (INACTIVE) |

4.1.1 MODE SWITCH

The MODE rotary switch controls power to the ventilator electronics and sets the ventilation control mode. The OFF position turns the power off to the ventilator. Turning the MODE switch counter clockwise one position, to STBY, turns on the power to the ventilator and places the ventilator in Standby (STBY). No controlled ventilation occurs in STBY. On switching from OFF, the ventilator first performs a selftest. Until the selftest is completed, no ventilation can occur, regardless of switch position. At the completion of the selftest, a pass/fail message is displayed.

WARNING: IF THE SELFTEST FAILS, DO NOT ATTEMPT TO USE THE VENTILATOR.

If the selftest fails, a selftest failed message and code, that identifies the failure, is displayed for 10 seconds. If the selftest passes, a selftest passed message is displayed for 3 seconds. The ventilator then enters the mode indicated by the MODE switch.

NOTE: It is recommended that when first powering up the ventilator (i.e., switching the MODE switch from the OFF position) that the MODE switch be set to STBY until the selftest is completed.

Setting the MODE switch to IMV or ASSIST starts controlled ventilation. IMV is controlled ventilation at the set BPM and I:E Ratio with no assisted breaths. ASSIST is controlled ventilation at the set BPM and I:E Ratio with assisted breaths delivered whenever the patient attempts to breath. Assisted breath negative pressure sensitivity can be set from -2 cmH₂O to -10 cmH₂O (below the end expiratory pressure) with 2 cmH₂O resolution.

WARNING: SET THE VENTILATION CONTROL PARAMETERS (BPM, I:E RATIO, V_T, AND %O₂) TO THE DESIRED POSITION BEFORE STARTING VENTILATION.

WARNING: IF ASSIST MODE IS SELECTED, MONITOR PERFORMANCE TO INSURE AUTO-CYCLING (UNINTENTIONAL ASSISTED BREATHS) DOES NOT OCCUR.

NOTE: If auto-cycling occurs (unintentional assist breaths delivered), set the MODE switch to a more negative assisted breath sensitivity.

4.1.2 TIDAL VOLUME SWITCH

The TIDAL VOLUME rotary switch controls the V_T in 50 ml increments from 200 ml to 1200 ml, counter clockwise increasing. Tidal Volume is measured at the patient wye and the flow is adjusted to match the TIDAL VOLUME switch setting. The Novamatrix FLOTRAK flow sensor is used to determine V_T to an accuracy of $\pm 3\%$. If the flow sensor is not attached, V_T is approximated based on a mechanical lung model with $C_{rs} = 0.05 \text{ l} \cdot \text{cmH}_2\text{O}$ and R_{p10} parabolic restrictor.

WARNING: THE FLOW SENSOR MUST BE ATTACHED FOR ACCURATE V_T READINGS.

It is possible to set a V_T that is not attainable because of the current BPM and I:E RATIO settings. For example, a V_T setting of 1200 ml with the BPM set at 28 and the I:E RATIO set at 1:5.5 is not attainable because of the short inspiration time (0.3 sec.). In this case, the LSTAT Ventilator displays a message that notifies the operator that the V_T setting is impossible to attain.

4.1.3 I:E RATIO SWITCH

The I:E RATIO rotary switch controls the ratio of inspiration time to expiration time. This ratio (I:E) can be varied from 2:1 (i.e., the inspiration time is twice the expiration time) to 1:5.5 (the expiration time is 5.5 times the inspiration time) in 0.5 increments. The inspiration and expiration times are determined with the following formulas:

$$\begin{aligned}\text{inspiration time-seconds} &= 60/(\text{BPM}(1 + \text{E/I})); \\ \text{expiration time-seconds} &= 60/\text{BPM} - \text{inspiration time}.\end{aligned}$$

4.1.4 BPM SWITCH

The BPM rotary switch controls the ventilation cycle time by setting the breaths per minute. The breaths per minute can be set from 5 to 28 in 1 breath per minute steps. The breath cycle time is determined by the following formula:

$$\text{cycle time-seconds} = 60/\text{BPM}.$$

4.1.5 %O₂ SWITCH

The %O₂ rotary switch controls the air/oxygen blender. The %O₂ can be set from 21% O₂ to 100% O₂. If the %O₂ switch is set to anything other than 21%, the ventilator displays a message that oxygen is in use. If O₂ is in use and O₂ pressure is lost, an alarm is generated and the blender is set to 21%O₂ (air only) to insure that adequate volume is delivered regardless of the %O₂ switch setting. Likewise, if inlet air pressure is lost, the LSTAT ventilator will automatically set the blender to 100%O₂, regardless of the %O₂ switch setting, to insure that ventilation continues.

4.1.6 ALARM MUTE SWITCH

The ALARM MUTE pushbutton switch is used to cancel alarm and notice messages and to stop the audible annunciation. Note that if the condition that caused the alarm is not corrected, the alarm will immediately sound again.

4.1.7 MANUAL BREATH SWITCH

The MANUAL BREATH pushbutton switch delivers a single breath (at the set V_T , %O₂, BPM and I:E RATIO) for each depression. A manual breath can be delivered at anytime, regardless of mode (STBY, IMV, or ASSIST) or breath phase (inspiratory or expiratory), as long as the ventilator is powered.

WARNING: THE VENTILATOR MUST BE POWERED (I.E. THE MODE MUST NOT BE OFF) FOR THE MANUAL BREATH MODE TO FUNCTION.

4.1.8 COMP SWITCH

The COMP switch normally controls the power to the LSTAT ventilator compressor. However, in this laboratory version, the compressor power is controlled by a separate power switch located on the compressor module. The Control Panel COMP switch is inactive.

NOTE: Turning the compressor ON at least 5 seconds prior to starting ventilation allows time for the reservoir to fill, thus preventing inlet pressure loss alarms.

NOTE: Turning the compressor OFF when not ventilating saves significant power.

4.2 GRAPHICS DISPLAY AND MATRIX TOUCHSCREEN

A 320 by 240 pixel Electroluminescent (EL) display panel provides the data and status readout function for the LSTAT Ventilator. The display is amber on a black background. Five operational screen formats are used. The screen format depends on the Ventilator mode of operation and the actions of the operator. The screen formats are as follows:

1. Normal Screen - refer to Figure 2
2. Change Screens - refer to Figure 3a and Figure 3b
3. Waveform Select Screen - refer to Figure 4
4. Waveform Display Screen - refer to Figure 5
5. Lowpower Screen - refer to Figure 6.

All screen formats (except the Lowpower Screen) display the following common information:

- | | |
|--|---|
| 1. Airway Pres. (AP) Gage, Range (Resolution, Accuracy) | -10 to 80 cmH ₂ O (1 cmH ₂ O, 1 cmH ₂ O) |
| 2. Peak Airway Pres. (PAP), Range (Resolution, Accuracy) | -10 to 80 cmH ₂ O (1 cmH ₂ O, 1 cmH ₂ O) |
| 3. V _T , Range (Resolution, Accuracy) | 200 to 1200 ml (1 ml, 3% of reading) |
| 4. E _T CO ₂ , Range (Resolution, Accuracy) | 0 to 100 mmHg (1 mmHg, 2 torr) |
| 5. SpO ₂ , Range (Resolution, Accuracy) | 80 to 100 % (1 %, 2%) |
| 6. Heart Rate, Range (Resolution, Accuracy) | 30 - 250 bpm (1 bpm, 1% of full scale) |

All screen formats also have in common a large "Window" area for displaying alarm and notice messages, change parameters and waveforms. The Window is closed (opaque) when no alarm or notice messages are active and when no change parameters or waveforms are displayed. The Window is opened when alarm or notice messages are displayed or when change parameters or waveforms are displayed.

The Matrix Touchscreen is overlaid on the EL Display and provides the "Touch Buttons" to set ventilation parameters and control Ventilator Display modes. Touch Buttons are button areas highlighted on the EL Display. The Touch Buttons shown in Figure 2 are listed as follows:

1. CHANGE SETTING
2. SELFTEST
3. LOWPOWER MODE
4. DISPLAY WAVEFORM

A finger touch within the button area will cause the ventilator to perform the Touch Button function. Touch Buttons operate in Touch and Release Mode:

1. Touch and Release (TR) - the button must be touched then released before the action occurs.

The following paragraphs describe the LSTAT Ventilator screen formats and the Touch Button controls.

4.2.1 NORMAL SCREEN

The Normal Screen format is the default screen format for the Ventilator. It is displayed when power is first applied to the Ventilator. Notice that there are two Touch Button configurations for the Normal Screen format; 1.) STANDBY and, 2.) ON/ASST and ON/IMV. The reason is that SELFTEST and LOWPOWER MODE can only be activated in STANDBY MODE while DISPLAY WAVEFORM can only be active when ventilating. Parameters can be changed at any time, thus the CHANGE SETTING Touch Button is always displayed and active.

If the CHANGE SETTING Touch Button is touched the Change Screen format is displayed. If the DISPLAY WAVEFORM Touch Button is touched, the Waveform Select Screen format is displayed. If the LOWPOWER MODE Touch Button is touched, the Lowpower Screen format is displayed.

4.2.2 CHANGE SCREEN

The Change screen format is displayed whenever the CHANGE SETTING Touch Button is touched. It displays all the parameters that can be changed in the Window area of the screen. Touch Buttons are displayed to control the changing of ventilation parameters. When changes are ended, the NORMAL SCREEN is displayed.

4.2.3 WAVEFORM SELECT SCREEN

The Waveform Select Screen is displayed when the DISPLAY WAVEFORM Touch Button is touched. This screen provides Touch Buttons to either select a waveform to be displayed or to cancel the waveform display. If a waveform is selected for display, the Waveform Display screen format is displayed. If the waveform is canceled, the Normal Screen format is displayed.

4.2.4 WAVEFORM DISPLAY SCREEN

The Waveform Display screen format is displayed whenever a waveform is selected from the Waveform Select screen. The selected waveform (CO₂, Pressure or Flow) is displayed in the Window. Touch Button controls are provided to change parameters, display other waveforms (or cancel the waveform display) and to change the waveform display y-axis (vertical) scale. The y-axis scales for the waveforms are as follows:

1. CO₂ Scale 0 to 100 mmHg in 10 mmHg increments.
2. Pressure Scale 1 -15 to 35 cmH₂O in 5 cmH₂O increments.
3. Pressure Scale 2 -30 to 70 cmH₂O in 10 cmH₂O increments.
4. Flow Scale 1 -60 to 40 l/min in 10 l/min increments.
5. Flow Scale 2 -120 to 80 l/min in 20 l/min increments.

The x-axis (horizontal) scale is fixed to display four seconds worth of the breath cycle regardless of the cycle time. The waveform display is continuous and real time.

4.2.5 LOWPOWER SCREEN

The Lowpower screen format is displayed when the LOWPOWER MODE Touch Button is touched. This screen format is blank, except for the message, "TOUCH HERE TO CANCEL POWER SAVE MODE". The blank screen saves significant power. Touching the screen anywhere returns the Normal Screen format.

4.2.6 TOUCH BUTTON CONTROLS

The following paragraphs describe the operation of each Touch Button.

4.2.6.1 CHANGE SETTING TOUCH BUTTON

The CHANGE SETTING Touch Button allows the operator to change the settings of ventilation parameters that are not accessible from the Control Panel. The parameters and their limits are as follows:

1. Maximum Pressure (PMAX) Limit: PMIN + 5 to 80 cmH₂O (1 cmH₂O steps)
2. Minimum Pressure (PMIN) Limit: 0 to PMAX - 5 cmH₂O (1 cmH₂O steps)
3. E_TCO₂ High Limit: E_TCO₂ Low Limit +10 to 100 mmHg (1 mmHg steps)
4. E_TCO₂ Low Limit: 0 to E_TCO₂ High Limit - 10 mmHg (1 mmHg steps)
5. E_TCO₂ Alarm: On/Off
6. SpO₂ Low Limit: 0 to 99 % (1 % steps)
7. SpO₂ Alarm: On/Off
8. Audible Alarm: On/Off
9. Inspiratory Hold Time: 0 to 30% (10% steps)
10. Pressure Units: cmH₂O, mmHg, kPa
11. Auto Vent: On/Off
12. PMAX Target: PMIN Target + 2 to 80 cmH₂O (1 cmH₂O steps)
13. PMIN Target: 0 to PMAX Target - 2 cmH₂O (1 cmH₂O steps)
14. E_TCO₂ Maximum: 0 to 100 mmHg (1 mmHg steps)
15. Delta BPM: 1 to 5 BPM (1BPM steps)
16. Check Time Interval: 1 to 5 minutes (1 minute steps)

Touching the CHANGE SETTING Touch Button causes the Change Screen to be displayed (refer to Figure 3). The Change Screen lists the parameters that can be changed and displays the following Touch Buttons to effect changes:

1. **INCREASE** - increases the value of the selected parameter one step.
2. **DECREASE** - decreases the value of the selected parameter one step.
3. **CURSOR** - changes the selected parameter to the next in the list.
4. **ENTER** - causes the change to take effect.

Parameters are selected using the cursor button. The blinking arrow cursor points to the parameter to be changed. The change value of the parameter appears in a message in the message window. Repeated touches of the cursor button cause the cursor to sequence through the list of parameters. When the Change Screen first appears, parameters 1 through 10 are listed in the message window along with their current setting. With the cursor pointing at parameter 10 (Units), and with a touch of the CURSOR button, the next set of parameters (11 through 16) are displayed for possible modification. Likewise, if the cursor is pointing at item 16 (Check Time), and the CURSOR button is touched, items 1 through 10 are listed again.

The INCREASE and DECREASE buttons are used to change the parameter value. If a parameter limit is reached, the message, "LIMIT REACHED.", is displayed. The parameter limit cannot be exceeded, therefore, repeated attempts to exceed the limit will not affect the parameter change value any further.

Parameter values are buffered and do not take effect until the ENTER Touch Button is touched. The updated value appears in a message line in the Window while the operating value of the parameter remains unchanged in the list. When the ENTER Touch Button is touched, the operating value in the parameter list is updated and the change takes effect. Parameters can be changed at any time, so the CHANGE SETTING Touch Button is visible and active in all screen formats (except the Change Screen). The Change Screen is exited when the screen is touched in the area of the Window (refer to Figure 3.).

NOTE: The CHANGE SETTING default parameter values are set as follows:

1. Maximum Pressure Limit: 40 cmH₂O
2. Minimum Pressure Limit: 3 cmH₂O
3. E_TCO₂ High Limit: 90 mmHg
4. E_TCO₂ Low Limit: 0 mmHg
5. E_TCO₂ Alarm: ON
6. SpO₂ Low Limit: 0%
7. SpO₂ Alarm: ON
8. Audible Alarm: ON
9. Inspiratory Hold Time: 0%
10. Pressure Units: cmH₂O
11. Auto Vent: OFF
12. P_{MAX} Target: 16 cmH₂O
13. P_{MIN} Target: 12 cmH₂O
14. E_TCO₂ Maximum: 50 mmHg
15. Delta BPM: 2
16. Check Time Interval: 1

WARNING: E_TCO₂ LOW LIMIT MUST BE SET TO ALARM ON NO OR LOW E_TCO₂.

WARNING: SpO₂ LOW LIMIT MUST BE SET TO ALARM ON NO OR LOW SpO₂.

4.2.6.2 SELFTEST TOUCH BUTTON

The SELFTEST Touch Button causes the Ventilator to perform a continuous selftest (the screen remains in the Normal Screen format). The Ventilator opens the Window and displays the message, "SELFTEST IN PROGRESS." when SELFTEST is touched. The Selftest runs continuously until the operator ends it by touching the CANCEL SELFTEST button or by switching the MODE to IMV or ASSIST.

The SELFTEST Touch Button is visible and active only in STANDBY Mode.

4.2.6.3 LOWPOWER MODE TOUCH BUTTON

The LOWPOWER MODE Touch Button causes the Ventilator to go into a power save mode and display the Lowpower Screen format (refer to Figure 6.). In this mode, the EL Display is blank (except for a message that says, "TOUCH HERE TO CANCEL POWER SAVE MODE.") and the processors are placed in idle mode that saves 40% power. Touching the screen anywhere ends the LOWPOWER MODE. Also, if the MODE Switch is changed from STBY, the LOWPOWER MODE is terminated and ventilation started.

The LOWPOWER MODE Touch Button is visible and active only in STANDBY Mode.

4.2.6.4 DISPLAY WAVEFORM TOUCH BUTTON

The DISPLAY WAVEFORM Touch Button causes the Waveform Select screen (refer to Figure 4) to be displayed. The DISPLAY WAVEFORM Touch Button is visible and active only when ventilating (not in STBY Mode). The Waveform Select screen provides the following Touch Buttons to select waveforms to be displayed in the Waveform Display Screen:

1. **CO2 WAVEFORM** - causes CO2 waveform to be displayed.
2. **PRESSURE WAVEFORM** - causes patient airway pressure waveform to be displayed.
3. **FLOW WAVEFORM** - causes flow waveform to be displayed.

The **CANCEL WAVEFORM** Touch Button ends the Waveform Display and causes the Normal Screen format to be displayed.

The Waveform Display Screen (refer to Figure 5.) provides three Touch Buttons to control the operation of the Ventilator. **CHANGE SETTINGS** is provided to change ventilation parameters when displaying waveforms. Parameters can be changed and the waveform can be displayed again when the changes are done. The **DISPLAY WAVEFORM** Touch Button is provided to change the waveform or to cancel the waveform display.

The **SCALE** Touch Button is active only if a Pressure waveform or Flow waveform is displayed. This Touch Button switches the scale of these waveforms as described in Section 4.2.4.

4.3 CHANGING PARAMETERS

V_T , breath rate (BPM), breath phase relationship (I:E RATIO), blend (%O₂) and Mode (STBY, IMV, ASST) are all controlled from the Control Panel. It is good practice to set these controls to the desired position before starting ventilation. **Once ventilation is started, parameters should be changed gradually to prevent step functions in delivered V_T .** The timing and phase changes effected by the BPM and I:E RATIO switches are instantaneous. However, because the flow valve is multi-turn (7 turns from closed to open), V_T adjustment is delayed. Therefore, it is possible to get a temporary increase or decrease in V_T if the BPM or I:E RATIO settings are drastically changed.

WARNING: TEMPORARY INCREASES OR DECREASES IN VT WILL RESULT IF THE BPM OR I:E RATIO SETTINGS ARE DRASTICALLY CHANGED.

Inspiratory Hold, P_{MAX}, P_{MIN}, Sensor high and low limits and audible alarm settings are all controlled from the Display Touchscreen. To change these parameters, the **CHANGE SETTING** Touch Button must be touched. The Change Screen is displayed that lists these parameters (refer to Figure 3). The Cursor highlights the first parameter in the list. Touch the **CURSOR** Touch Button to move the Cursor to the desired parameter in the list. Figure 3 shows the Cursor on the EtCO₂ HI limit alarm setting. Touch the **INCREASE** or **DECREASE** Touch button to change the value of the parameter. As the **INCREASE** or **DECREASE** Touch Buttons are touched, the new value of the parameter is displayed in a message above the parameter list. The current operating value in the list remains unchanged. Figure 3 shows EtCO₂ HI being decreased to 60 mmHg. Note the current operating value is still 80 mmHg. The operating value is not changed until **ENTER** is touched.

Multiple parameters can be changed before touching **ENTER**, at which time they are changed simultaneously. The changed values are saved in a temporary location until **ENTER** is touched. To end the change session, touch in the location of the, "TO END CHANGES, TOUCH HERE", message. If **ENTER** is not touched before the end message is touched, no changes are made.

4.4 AUTOMATIC MODE OF OPERATION

The LSTAT Ventilator for the Mayo Clinic provides an automatic mode of ventilation that alters ventilation based on patient response and target control parameters set by the operator. The control parameters are:

1. **TARGET PEAK AIRWAY PRESSURE.** The LSTAT Ventilator automatically adjusts flow to achieve a target peak airway pressure reading set by the operator.
2. **MAXIMUM EtCO₂.** The LSTAT Ventilator automatically increases BPM if the EtCO₂ reading exceeds an adjustable maximum EtCO₂ set by the operator. The rate of the BPM increase is adjustable. The step increase in BPM can be varied from 1 to 5 BPM, and the sampling time for step increases can be varied from 1 to 5 minutes. When the EtCO₂ reading is less than the maximum setting, the BPM is held constant.

The Automatic Mode control parameters that are set by the operator are as follows:

- | | |
|--|---|
| 1. Auto Vent | ON/OFF |
| 2. P _{MAX} Target, range (resolution) | P _{MIN} Target + 2 to 80 cmH ₂ O (1 cmH ₂ O) |
| 3. P _{MIN} Target, range (resolution) | 0 to P _{MAX} Target - 2 cmH ₂ O (1 cmH ₂ O) |
| 4. EtCO ₂ Maximum, (resolution, accuracy) | 0 to 100 mmHg (1 mmHg, ± 2 torr) |
| 5. Delta BPM | 1 to 5 BPM |
| 6. Check Time Interval | 1 to 5 Minutes |

The default values for the Automatic Mode control parameters are as follows:

1. Auto Vent: OFF
2. P_{MAX} Target: 16 cmH₂O
3. P_{MIN} Target: 12 cmH₂O
4. E_TCO₂ Maximum: 50 mmHg
5. Delta BPM: 2
6. Check Time Interval: 1

The Automatic Mode is started by setting the AUTO VENT control parameter (refer to Figure 3b) to ON. Refer to Section 4.2.6.1 and Section 4.3 for instructions on changing parameters. When Automatic Mode ventilation is first started, ventilation is at the V_T, BPM, I:E RATIO, O₂ LEVEL and MODE set on the Control Panel switches. However, as patient parameters are monitored the V_T and BPM can be altered, automatically, by the Ventilator.

The LSTAT Ventilator automatically adjusts flow (V_T) to achieve a target peak airway pressure reading set by the operator. This target is halfway between the Target P_{MAX} and Target P_{MIN} settings:

$$\text{Target PAP} = \text{P}_{\text{MIN}} \text{ Target} + (\text{P}_{\text{MAX}} \text{ Target} - \text{P}_{\text{MIN}} \text{ Targe})/2$$

When Automatic Mode is started, the message, "AUTO VENT ON. TARGET PRESSURE: 14 cmH₂O", is displayed (14 cmH₂O is the default Target PAP). If the Target P_{MAX} or Target P_{MIN} are changed the message displays the changed Target PAP accordingly. If the actual measured PAP is greater than the Target P_{MAX} setting, the following message is displayed, "TARGET P_{MAX} EXCEEDED. DECREASING V_t.", and the flow is automatically decreased. Likewise, if the actual measured PAP is less than the Target P_{MIN} setting, the following message is displayed, "TARGET P_{MIN} NOT ATTAINED. INCREASING V_t.", and the flow is automatically increased. If the actual measured PAP is less than or equal to the Target P_{MAX} setting and greater than or equal to the Target P_{MIN} setting, no message, other than the auto vent on message, is displayed. The flow, and therefore V_T, is adjusted until measured PAP equals the Target PAP. Therefore, the actual V_T delivered to the patient (shown on the EL display) may not match what is set on the TIDAL VOLUME switch.

NOTE: In Automatic Mode, the delivered V_T may not equal the TIDAL VOLUME switch setting.

NOTE: The Target P_{MAX} must be less than the set maximum pressure limit. Otherwise, a maximum pressure exceeded alarm condition could result.

In Automatic Mode, if the set EtCO₂ Maximum is exceeded the Ventilator automatically increases the BPM and displays the message, "CO2MAX EXCEEDED. INCREASING BPM TO: nn" (nn is the new BPM). The new BPM is set to:

$$\text{new BPM} = \text{Old BPM} + \text{Delta BPM}$$

When a new BPM is automatically set, the Ventilator does not check the EtCO₂ again until the set Check Time Interval elapses. If at the end of the time interval the set EtCO₂ Maximum is not exceeded, the BPM remains unchanged and the EtCO₂ is again monitored at the end of each breath to insure the maximum is not exceeded. However, if at the end of the time interval, the set EtCO₂ Maximum is again exceeded, the Ventilator automatically increases the BPM again and displays the new BPM. This process continues until the measured EtCO₂ remains less than the set EtCO₂ Maximum or until a maximum of 40 BPM is delivered. Therefore, the BPM delivered may not be the same as that set on the BPM switch. If the BPM switch is changed during Automatic Mode, the BPM delivered is reset to the switch reading and the EtCO₂ is monitored at the end of each breath to insure the maximum is not exceeded.

NOTE: In Automatic Mode, the delivered BPM may not equal the BPM switch setting.

NOTE: In Automatic Mode, the I:E RATIO remains unchanged.

NOTE: The EtCO₂ Maximum must be less than the set EtCO₂ High limit. Otherwise, an EtCO₂ High limit exceeded alarm condition could result.

Automatic Mode can be set for both IMV and ASSIST Modes of operation. The Automatic Mode algorithm monitors PAP and EtCO₂ for assisted breaths just as it does for Control and IMV breaths. When Automatic Mode is turned off, the delivered VT and BPM are reset to the switch settings. The Ventilator adjusts the flow to match the TIDAL VOLUME switch setting with the cycle time determined by the BPM switch.

WARNING: PMAX LIMIT AND PMAX TARGET MUST BE SET TO INSURE VITAL CAPACITY IS NOT EXCEEDED IN AUTOMATIC MODE.

5. VENTILATOR ALARMS

The LSTAT Ventilator continuously checks for alarm conditions. If an alarm condition is detected, the Ventilator:

1. Sounds a two tone audible alarm,
2. flashes the red ALARM light on the Control Panel,
3. and, flashes an alarm message on the EL Display.

The ALARM MUTE pushbutton is used to cancel the above listed alarm notifications. Alarms can also be cleared by touching the touchscreen in the message window area. However, if the condition that caused the alarm is not rectified, the alarm will sound again. The Ventilator will continue to operate and ventilate with alarms active. It is up to the operator to determine the cause of the alarm and rectify the situation. However, if a "VENTILATOR HARDWARE FAULT ALARM" is generated, the Ventilator must be replaced immediately.

WARNING: OPERATING THE VENTILATOR WITH THE "VENTILATOR HARDWARE FAULT ALARM" ACTIVE COULD RESULT IN PERSONAL INJURY.

5.1 ALARM CONDITIONS

Alarms are generated when a threshold is reached or fault is detected. Some alarm thresholds are adjustable so alarm conditions are grouped in two categories, Non-adjustable and Adjustable. The LSTAT Ventilator alarm conditions are listed as follows:

Non-Adjustable Alarm Conditions

1. Inlet Air Pressure Drop, Threshold (Accuracy) 15 psi (± 2 psi)
2. Oxygen Pressure Drop, Threshold (Accuracy) 25 psi (± 2 psi)
3. $E_T\text{CO}_2$ Sensor Hardware Fault
4. Flow Sensor Hardware Fault
5. SpO_2 Sensor Hardware Fault
6. Ventilator Controller Hardware Fault
7. CO2 Sensor Calibration Required Alarm

Adjustable Alarm Conditions

- | | |
|--|--|
| 1. P _{MAX} , Range (Resolution, Accuracy) | P _{MIN} + 5 to 80 cmH ₂ O (1 cmH ₂ O, ± 1 cmH ₂ O) |
| 2. P _{MIN} , Range (Resolution, Accuracy) | 0 to P _{MAX} - 5 cmH ₂ O (1 cmH ₂ O, ± 1 cmH ₂ O) |
| 3. $E_T\text{CO}_2$ Hi, Range (Resolution, Accuracy) | $E_T\text{CO}_2$ Lo + 10 to 100 mmHg (1 mmHg, ± 2 torr) |
| 4. $E_T\text{CO}_2$ Lo, Range (Resolution, Accuracy) | 0 to $E_T\text{CO}_2$ Hi - 10 mmHg (1 mmHg, ± 2 torr) |
| 5. SpO_2 Lo, Range (Resolution, Accuracy) | 0 to 100 % (1 %, ± 2 %) |

Inlet Air Pressure Drop alarm detects if the pneumatic driving air pressure drops below the threshold for switching the pneumatic valves (15 psi). This alarm indicates a problem with the Compressor or external air source. Not only is an alarm generated, but the Blender is turned to 100% O₂ to insure adequate volume reaches the patient. The oxygen pressure drop alarm is set at 25 psi to give ample warning of low oxygen capacity remaining in the bottles. Again, not only is an alarm generated but the Blender is set at 21% O₂ to insure adequate V_T. The Sensors ($E_T\text{CO}_2$, SpO_2 and Flow) and Ventilator Controller all perform a continuous background fault check and generate a Hardware fault alarm if a fault is detected. The Ventilator Controller performs a continuous check on all critical components. It continuously checks for shorts or open circuits in the pneumatic valves, continuously checks the thresholds on the pressure transducers and performs continuous checks on key ventilator control parameters to ensure they are within valid ranges. The CO₂ Sensor continuously checks its threshold values and generates a calibration required alarm if they are out of range.

The P_{MAX} and P_{MIN} alarms are used to monitor patient pressure. If P_{MAX} is exceeded, not only is an alarm generated, but a "DUMP" Pressure Valve is activated that opens the patient circuit to atmosphere. This "Dump" valve acts as an electronic pressure relief valve and provides a fail safe mechanism that prevents excessive pressure being delivered to the patient. The default P_{MAX} is 40 cmH₂O. The P_{MIN} alarm is used to verify that a minimum pressure is achieved. P_{MIN} is useful for detecting leaks. The default P_{MIN} is 3 cmH₂O.

WARNING: IF P_{MIN} IS SET TO 0 CMH₂O, LEAKS WILL NOT BE DETECTED.

The $E_T\text{CO}_2$ Hi, $E_T\text{CO}_2$ Lo and SpO_2 Lo alarms are used to monitor ventilation effectiveness. The $E_T\text{CO}_2$ High Limit default is 90 mmHg. The $E_T\text{CO}_2$ Low Limit default is 0 mmHg. The SpO_2 Low Limit default is 0%.

WARNING: $E_T\text{CO}_2$ LOW LIMIT MUST BE SET TO ALARM ON NO OR LOW $E_T\text{CO}_2$.

WARNING: SpO_2 LOW LIMIT MUST BE SET TO ALARM ON NO OR LOW SpO_2 .

If multiple alarm conditions occur simultaneously, they are all stored. Each alarm must be individually cleared. Every alarm condition is signified with a unique alarm message that informs the operator of the alarm situation. If parameter changes are not being made or if waveforms are not displayed, all alarm messages appear simultaneously in the message window. However, if the Change Screen or Waveform Screen is active, only the highest priority alarm is displayed because of the limited display area. As alarms are cleared, the next highest priority alarm message is displayed until all alarms are cleared. When all alarms are cleared, the message window closes, the red alarm LED is turned off, and the audible ceases to sound.

5.2 ALARM MESSAGES

There is a unique alarm message displayed for each alarm. This message is flashed, one second on, one second off, in the message window until the alarm is cleared. The LSTAT Ventilator alarm messages are listed as follows:

<u>Alarm Condition</u>	<u>Message</u>
Inlet Air Pressure Drop	"INLET PRESSURE LOSS ALARM."
Oxygen Pressure Drop	"OXYGEN PRESSURE LOSS ALARM."
$E_T\text{CO}_2$ Sensor Hardware Fault	"CO2 SENSOR HARDWARE FAULT ALARM."
Flow Sensor Hardware Fault	"FLOW SENSOR HARDWARE FAULT ALARM."
SpO_2 Sensor Hardware Fault	"SpO2 SENSOR HARDWARE FAULT ALARM."
CO2 Sensor Calibration Required Alarm	"CO2 SENSOR CALIBRATION REQUIRED ALARM."
Ventilator Controller Hardware Fault	"VENTILATOR HARDWARE FAULT ALARM.";
PMAX	"MAXIMUM PRESSURE LIMIT ALARM."
PMIN	"MINIMUM PRESSURE LIMIT ALARM."
$E_T\text{CO}_2$ Hi	"EtCO2 HIGH LIMIT ALARM."
$E_T\text{CO}_2$ Lo	"EtCO2 LOW LIMIT ALARM."
SpO_2 Lo	"SpO2 LOW LIMIT ALARM."

5.3 AUDIBLE ALARM CONTROL

The audible annunciation of alarms can be enabled or disabled. Two levels of audible alarm control are provided. First, all audible annunciation of alarms can be enabled or disabled. Second, only the audible alarms associated with the CO_2 Sensor high and low limits can be enabled or disabled, and only the audible alarms associated with the SpO_2 Sensor low limit can be enabled or disabled.

Audible alarms are controlled by touching the CHANGE SETTING Touch Button. The audible alarm state is listed in the Change Screen parameter list (refer to Figure 3). The list item labeled AUDIBLE controls the state of all audible alarms. The item labeled EtCO₂ ALRM controls only the audible alarm associated with the CO_2 Sensor high and low limits. The item labeled SpO₂ ALRM controls only the audible alarm associated with the SpO_2 Sensor low limit. As shown in Figure 3, the audible alarms are either ON or OFF. Placing the Cursor on the appropriate audible alarm control list item and touching either INCREASE or DECREASE toggles the audible alarm state On or Off. Touching ENTER locks in the audible alarm state.

WARNING: TURNING OFF AUDIBLE ALARMS COULD RESULT IN PERSONAL INJURY.

5.4 VENTILATOR HARDWARE FAULT CODES

If a "VENTILATOR HARDWARE FAULT ALARM" is generated, it is possible to determine the cause of the hardware fault. Immediately replace the faulty ventilator, then cycle the power to the faulty unit (i.e.: turn the power off then back on). This causes the ventilator to perform the power on self test. This selftest not only tests the Ventilator control processor, but also tests the critical pneumatic components such as the blender, the flow control valve, the solenoid valves and the pressure sensors. At the completion of this test, the message, " nn SELFTEST FAILED. DO NOT USE." appears. The nn is a Fault Code. The Ventilator Fault Codes are listed as follows:

Fault Code

1. PROGRAM FAULT
2. MEMORY FAULT
3. ATOD FAULT
4. COMMAND FAULT
5. RECEIVE COMMAND FAULT
6. SWITCH FAULT
7. PRESSURE SENSOR FAULT
8. TOUCHSCREEN FAULT
9. SERIAL FAULT
10. ISR FAULT
11. OPCODE FAULT
12. PHASE FAULT
13. PRESSURE SENSOR FAULT
14. SOLENOID VALVE FAULT
15. GRAPHIC TIMEOUT FAULT
16. GRAPHIC FAULT
17. STATE FAULT
18. CURSOR FAULT
19. BLENDER FAULT
20. FLOW VALVE FAULT
21. MODE FAULT

6. VENTILATOR NOTICES

The LSTAT Ventilator displays notice messages to inform the operator of important situations. When a notice message is displayed on the EL Display the NOTICE light on the Control Panel is illuminated. Notice messages fall into two general categories; 1.) forewarning of an alarm and, 2.) general information. If the notice is a forewarning, the audible annunciator sounds, for 1/2 second, for each breath cycle. If the notice is for general information, the audible annunciator sounds just one time for 1/2 second. Notice messages are cleared by pressing the ALARM MUTE pushbutton on the Control Panel or by touching the Touchscreen. The notice message will reappear if the situation that caused the notice is not rectified.

6.1 FOREWARNING NOTICES

Forewarning notices are generated when a limit is approached. The following is a list of forewarning messages and their cause:

- | | |
|--|---|
| 1. "PEAK PRESSURE NEAR MAXIMUM" | Airway pressure is within 5 cmH ₂ O of set P _{MAX} limit. |
| 2. "PEAK PRESSURE NEAR MINIMUM" | Airway pressure is within 5 cmH ₂ O of set P _{MIN} limit. |
| 3. "EtCO ₂ NEAR HIGH LIMIT" | EtCO ₂ is within 5 mmHg of set EtCO ₂ HI limit. |
| 4. "EtCO ₂ NEAR LOW LIMIT" | EtCO ₂ is within 5 mmHg of set EtCO ₂ LO limit. |
| 5. "SpO ₂ NEAR LOW LIMIT" | SpO ₂ is within 5% of set SpO ₂ LO limit. |

6.2 GENERAL INFORMATION NOTICES

General information notices are either sensor related or ventilator related. The following list is the sensor related general information notice messages and their cause:

- | | |
|--|---|
| 1. "SPO ₂ PROBE OFF PATIENT" | The finger probe is not attached to the patients finger. |
| 2. "SPO ₂ PROBE ATTACHED" | The finger probe is correctly attached. |
| 3. "SPO ₂ SENSOR NOT CONNECTED" | The SpO ₂ sensor is not plugged into the ventilator. |
| 4. "CO ₂ SENSOR WARM UP IN PROGRESS" | The CO ₂ sensor is warming up. |
| 5. "CO ₂ SENSOR READY" | The CO ₂ sensor is warmed up and calibrated. |
| 6. "CO ₂ SENSOR NOT CONNECTED" | The CO ₂ sensor is not plugged into the ventilator. |
| 7. "CO ₂ CELL ZERO REQUIRED" | The CO ₂ sensor requires calibration (Section 7.2.2) |
| 8. "CO ₂ ADAPTER ZERO REQUIRED" | The CO ₂ sensor requires calibration (Section 7.2.2) |
| 9. "CO ₂ REFERENCE CHECK REQUIRED" | The REF cell is attached to sensor (Section 7.2.2) |
| 10. "CO ₂ CELL ZERO IN PROGRESS" | Cell zero calibration is in progress (Section 7.2.2) |
| 11. "CO ₂ ADAPTER ZERO IN PROGRESS" | Adapter calibration is in progress Section 7.2.2) |
| 12. "CO ₂ ZERO SUCCESSFUL" | Zero successfully completed. |
| 13. "CO ₂ ZERO NOT SUCCESSFUL" | Zero not successful (refer to Section 7.2.2) |
| 14. "CO ₂ REFERENCE IN PROGRESS" | CO ₂ reference check in progress (Section 7.2.2) |
| 15. "CO ₂ REFERENCE CHECK SUCCESSFUL" | CO ₂ reference check completed successfully |
| 16. "CO ₂ REFERENCE CHECK FAILED" | CO ₂ reference check failed (refer to Section 7.2.2) |
| 17. "nn mmHg REFERENCE CHECK RESULT" | nn is the reference check result (refer to Section 7.2.2) |
| 18. "ADAPTER MUST BE FREE OF CO ₂ " | Displayed before adapter zero is started. |
| 19. "ATTACH ZERO CELL" | The CO ₂ sensor requires calibration |
| 20. "REMOVE CELL TO CONTINUE" | Prompt to the user to remove cell at zero completion. |
| 21. "FLOW SENSOR NOT CONNECTED" | The flow sensor is not plugged into the ventilator. |
| 22. "INEXACT Vt." | The flow sensor is not plugged into the ventilator. |
| 23. "FLOW SENSOR READY" | The flow sensor is plugged into ventilator. |
| 24. "PRESS HERE OR ALARM MUTE TO START" | Prompt to the operator to start a calibration or check. |
| 25. "Vt DATA OUT OF RANGE." | Flow sensor clogged or not attached. |
| 26. "CHECK FLOW SENSOR." | Flow sensor clogged or not attached. |
| 27. "FLOW SENSOR Vt DISPLAYED AND DELIVERED." | Flow sensor data back in range. |

The following list is the ventilator related general information notice messages and their cause:

- | | |
|---|---|
| 1. "OXYGEN IN USE" | The %O ₂ switch is not set at 21%. |
| 2. "IMPOSSIBLE V _t SETTING" | The set V _T is invalid based on the BPM and I:E RATIO. |
| 3. "POSITIVE END EXPIRATORY PRESSURE" | PEEP detected. |
| 4. "INVERSE I:E RATIO. MONITOR PRESSURE" | Inverse I:E Ratio set. |
| 5. "ASSISTED BREATH DELIVERED" | Patient breathed and received an assisted breath. |
| 6. "MANUAL BREATH DELIVERED" | MANUAL BREATH pushbutton pressed. |
| 7. "AIR COMPRESSOR IS ON" | Compressor turned on. |
| 8. "AIR COMPRESSOR IS OFF" | Compressor turned off. |
| 9. "PMIN IS 0. LEAKS NOT DETECTED" | PMIN limit is set at zero. |
| 10. "LIMIT REACHED" | Range limit of a parameter being changed is reached. |
| 11. "TO END CHANGES, TOUCH HERE" | Prompt to the operator for ending change session. |
| 12. "TO CHANGE nn TO: nn; TOUCH ENTER" | Change parameter prompt message. |
| 13. "SELFTEST IN PROGRESS" | Selftest is in progress and Ventilator not ready. |
| 14. "SELFTEST PASSED" | Selftest passed and Ventilator is ready. |
| 15. "nn SELFTEST FAILED. DO NOT USE" | Selftest failed. nn is failure code. |
| 16. "nnn mmHg BAROMETRIC PRESSURE" | nnn is the Barometric pressure. |
| 17. "AUTO VENT ON. TARGET PRESSURE:" | Automatic mode status message. |
| 18. "CO ₂ MAX EXCEEDED. INCREASING BPM TO:" | Automatic mode status message. |
| 19. "TARGET P _{MAX} EXCEEDED. DECREASING V _t ." | Automatic mode status message. |
| 20. "TARGET P _{MIN} NOT ATTAINED. INCREASING V _t ." | Automatic mode status message |

WARNING: THE OXYGEN IN USE MESSAGE ONLY REFERS TO THE %O₂ SWITCH ON THE CONTROL PANEL. IT IS UP TO THE OPERATOR TO INSURE THE OXYGEN VALVE (REFER TO SECTION 7.4) IS SET CORRECTLY.

7. VENTILATOR CONNECTIONS

The LSTAT Ventilator provides connections to the Patient Tubing Circuit and to the Ventilator Sensors. In addition, an external air source connector is provided so the LSTAT Ventilator can be externally driven and a metered O₂ outlet valve is provided for direct application of oxygen via nasal cannula or mask.

7.1 PATIENT TUBING CIRCUIT

Three pneumatic connectors (keyed by size) are provided for the Patient Tubing Circuit:

1. Patient Breathing Tube Connector- largest diameter
2. Patient Pressure Tube Connector - middle diameter
3. Exhalation Valve Tube Connector - smallest diameter

These connectors match the size of the tubes on the Patient Tubing Circuit. The Patient Pressure Tube connects to the patient wye and is used to sense airway pressure. Airway pressures from -10 cmH₂O to 140 cmH₂O are sensed and displayed. The Exhalation Valve Tube connects to the Exhalation Valve and controls the opening and closing of the exhalation valve. Only the Bird #999-2576 valve is approved for use on the Patient Circuit. The Patient Breathing Tube connects to the endo tracheal tube.

For PEEP use the Bird or Ambu PEEP valves.

CAUTION: AIRWAY PRESSURE ABOVE 250 CMH₂O OR BELOW -200 CMH₂O WILL DAMAGE THE VENTILATOR.

WARNING: THE BIRD#999-2576 EXHALATION VALVE MUST BE USED. OTHER EXHALATION VALVES WILL NOT FUNCTION PROPERLY.

7.2 SENSORS

Three electronic/pneumatic connectors (keyed by size and shape) are provided for the LSTAT Ventilator sensors:

1. Novamatrix Ventrak Flow Sensor Connector.
2. Novamatrix Capnostat Co2 Sensor Connector.
3. Novamatrix OXYSNAP Extension Cable Connector.

These connectors match the size and shape of the sensor mating connectors.

CAUTION: THE NOVAMETRIX VENTRAK (CATALOG NO. 7222) FLOW SENSOR MUST BE USED. OTHER FLOW SENSORS WILL NOT FUNCTION PROPERLY AND WILL DAMAGE THE VENTILATOR.

CAUTION: THE NOVAMETRIX CAPNOSTAT (CATALOG NO. 7167) CO2 SENSOR MUST BE USED. OTHER CO2 SENSORS WILL NOT FUNCTION PROPERLY AND WILL DAMAGE THE VENTILATOR.

CAUTION: THE NOVAMETRIX OXYSNAP (CATALOG NO. 8744) FINGER SENSOR MUST BE USED. OTHER SPO2 SENSORS WILL NOT FUNCTION PROPERLY AND WILL DAMAGE THE VENTILATOR. THE OXYSNAP CONNECTS TO THE VENTILATOR VIA THE OXYSNAP EXTENSION CABLE(CATALOG NO. 8853).

7.2.1 VENTRAK PEDIATRIC/ADULT FLOW SENSOR

This flow sensor is intended for use on patients with endotracheal tube sizes greater than 4.0 mm. The VENTRAK (Catalog No. 7222) consists of a sensor connected by tubing to a connector plug. The connector plug "snaps" into the LSTAT Flow Sensor connector. The sensor itself is installed at the proximal end of the patient circuit between the elbow and the patient wye. The smaller diameter end of the sensor faces the ventilator and the larger diameter end goes to the patient wye. Ensure the sensor tubing exits in an upward direction. The Flow Sensor does not need to be calibrated.

WARNING: ENSURE THE INTEGRITY OF THE PATIENT CIRCUIT AFTER INSTALLING THE FLOW SENSOR.

WARNING: DO NOT REUSE THE FLOW SENSOR. STERILIZATION MAY COMPROMISE PERFORMANCE.

If the Flow Sensor is not connected to the LSTAT Ventilator, the following message is displayed; "FLOW SENSOR NOT CONNECTED. INEXACT Vt.". The V_T delivered is inexact because actual flow is not measured, but approximated based on a mechanical lung model with $C_{rs} = 0.05 \text{ l}^{-1} \text{ cmH}_2\text{O}$ and R_{P10} parabolic restrictor. Likewise, if the flow sensor is faulty or the flow data out of range (due to a clogged sensor), the V_T delivered and displayed is approximated.

If the Flow Sensor is faulty, the alarm message, "FLOW SENSOR HARDWARE FAULT ALARM.", is displayed. If the flow Sensor data is out of range, the message, "Vt DATA OUT OF RANGE. CHECK FLOW SENSOR.", is displayed. If the Flow Sensor is not plugged into the Ventilator, the message, "FLOW SENSOR NOT CONNECTED", is displayed. When the Flow Sensor is connected, the message, "FLOW SENSOR READY.", is displayed.

7.2.2 CAPNOSTAT CO₂ SENSOR

The CAPNOSTAT CO₂ sensor is intended for use on patients with endotracheal tube sizes greater than 4.0 mm. This sensor consists of a CAPNOSTAT (that snaps into an airway adapter) connected by cable to an electronic plug and a CAPNOSTAT Disposable Adult Airway Adapter (Catalog No. 6063). The electronic plug snaps into the LSTAT Ventilator CO₂ Sensor Connector. The CAPNOSTAT snaps into the Disposable Adult Airway Adapter. It is keyed and will only snap in when correctly aligned. The Airway Adapter is installed at the proximal end of the patient circuit between the elbow and the patient wye. For optimal results, DO NOT place the adapter between the endotracheal tube and the elbow.

NOTE: On the CAPNOSTAT Cable are two calibration cells. One is labeled, "REF" and the other is labeled, "0". REF is the Reference Cell which is used to perform periodic sensor reference checks. 0 is the ZERO CELL which is used to "zero" the sensor during calibration.

WARNING: ENSURE THE INTEGRITY OF THE PATIENT CIRCUIT AFTER INSTALLING THE CO₂ SENSOR AIRWAY ADAPTER.

WARNING: DO NOT REUSE THE CO₂ AIRWAY ADAPTER. STERILIZATION MAY COMPROMISE PERFORMANCE.

If the CO₂ Sensor is not connected to the LSTAT Ventilator, the following message is displayed; "CO₂ SENSOR NOT CONNECTED". The displayed EtCO₂ will read 0 mmHg when the CO₂ sensor is not connected to the Ventilator. The CO₂ Sensor requires a minute or two warm-up before it will operate when power is turned on to the Ventilator. The Ventilator displays the message, "CO₂ SENSOR WARM UP IN PROGRESS.", while the sensor is warming up. The Ventilator displays the message, "CO₂ SENSOR READY", when the warm-up is complete.

WARNING: THE CO₂ SENSOR MUST BE CALIBRATED WHEN FIRST INSTALLED.

When a new CO₂ Sensor is connected to the LSTAT Ventilator, a "CO₂ SENSOR CALIBRATION REQUIRED ALARM" is generated along with the message, "CO₂ CELL ZERO REQUIRED. ATTACH ZERO CELL TO START CELL ZERO". The procedure for performing a Cell ZERO is as follows:

1. Remove the CAPNOSTAT from the Airway Adapter and snap it into the ZERO CELL. The Ventilator will prompt the operator with a message to depress the ALARM MUTE button or to touch the Touchscreen to start the Cell ZERO.
2. The Ventilator displays the message, "CO₂ CELL ZERO IN PROGRESS." after the operator initiates the zero. The cell ZERO can take up to 20 seconds to complete. At the completion of the Cell ZERO, the Ventilator displays the message, "CO₂ ZERO SUCCESSFUL." or the message, "CO₂ ZERO NOT SUCCESSFUL. TRY AGAIN"
3. If the Cell ZERO was not successful, repeat steps 1 and 2 again. If the zero continues to result in a not successful message, the CAPNOSTAT Sensor is faulty and must be replaced.
4. If the Cell ZERO was successful, remove the CAPNOSTAT from the ZERO CELL and snap it back onto the Airway Adapter.

In most cases a "CO₂ SENSOR CALIBRATION REQUIRED ALARM" will again be generated along with the message, "CO₂ ADAPTER ZERO REQUIRED. INSURE ADAPTER FREE OF CO₂ BEFORE START.". The procedure for performing an Adapter ZERO is as follows:

1. The Ventilator will prompt the operator with a message to depress the ALARM MUTE button or to touch the Touchscreen to start the Adapter ZERO. The Airway Adapter, with the CAPNOSTAT attached to it, must be removed from the patient circuit and be free of CO₂ during this procedure.
2. The Ventilator displays the message, "CO₂ ADAPTER ZERO IN PROGRESS." after the operator initiates the zero. The Adapter ZERO can take up to 20 seconds to complete. At the completion of the Adapter ZERO, the Ventilator displays the message, "CO₂ ZERO SUCCESSFUL." or the message, "CO₂ ZERO NOT SUCCESSFUL. TRY AGAIN."
3. If the Adapter ZERO was not successful, repeat steps 1 and 2 again. If the zero continues to result in a not successful message, the CAPNOSTAT Sensor is faulty and should be replaced.
4. If the Adapter ZERO was successful the CAPNOSTAT is ready.

WARNING: IF CO₂ IS PRESENT DURING AN ADAPTER ZERO, CO₂ READINGS WILL BE ERRONEOUS.

Normally, CO₂ Sensor calibration is required only when the Ventilator generates a "CO₂ SENSOR CALIBRATION REQUIRED ALARM". However, the operator can initiate a Cell ZERO calibration at any time by simply attaching the CAPNOSTAT to the ZERO CELL. Also, CO₂ Sensor calibration is required if the Reference Check is out of range.

NOTE: A CO₂ Sensor Reference Check should be performed periodically to verify the correct operation of the sensor.

The procedure for performing a Reference Check is as follows:

1. Remove the CAPNOSTAT from the Airway Adapter and snap it into the REF CELL. The Ventilator will display the message, "CO₂ REFERENCE CHECK REQUIRED" and will prompt the operator with a message to depress the ALARM MUTE button or to touch the Touchscreen to start the Reference Check.
2. The Ventilator displays the message, "CO₂ REFERENCE CHECK IN PROGRESS." after the operator initiates the check. The Reference Check can take up to several seconds to complete. At the completion of the check, the Ventilator displays the message, "CO₂ REFERENCE CHECK SUCCESSFUL." or the message, "CO₂ REFERENCE CHECK NOT SUCCESSFUL.", along with the reference check result. The result must be 38 mmHg \pm 2 mmHg.
3. If the Reference Check was not successful, perform a Cell ZERO.
4. If the Reference Check was successful, remove the CAPNOSTAT from the REF CELL and snap it back onto the Airway Adapter. The CAPNOSTAT is ready.

7.2.3 OXYSNAP SpO₂ FINGER SENSOR AND EXTENSION CABLE

The SpO₂ sensor consists of the OxySnap Finger sensor and the OxySnap Extension Cable. The male end of the Extension cable plugs into the LSTAT Ventilator while the female end attaches to the Finger Sensor plug. The Finger Sensor itself contains a placement guide to aid in sensor application. Position the tip of the finger against the placement guide with the finger nail towards the red light source (cable exits above the finger when placed correctly). The SpO₂ sensor does not need to be calibrated.

NOTE: The Finger Sensor is intended for use on adult fingers and is not designed for neonatal or pediatric patients.

If the Finger Sensor is not connected to the LSTAT Ventilator, the following message is displayed; "SpO₂ SENSOR NOT CONNECTED.". If the Finger Sensor is not attached to the patient, the following message is displayed, "SpO₂ PROBE OFF PATIENT.". In both these cases the SpO₂ displayed is 0%. When the SpO₂ is attached to the patient and connected to the Ventilator, the SpO₂ and the heart rate are displayed.

7.3 AIR SOURCE CONNECTION

A standard 1/8 in. ID tube is provided, on the Pneumatic Module, for attaching an external air source to the LSTAT Ventilator. This Tube is labeled "Air" and is normally connected to the reservoir output from the Compressor Module (refer to Figure 7a) . The Air tube can also be connected to or teed to an external air source. Check valves in the pneumatic circuit prevent the external air from flowing back into the compressor.

WARNING: THE EXTERNAL AIR SOURCE MUST BE REGULATED TO AT LEAST 30 PSI AND NO GREATER THAN 60 PSI.

7.4 OXYGEN SOURCE CONNECTION

Oxygen input is provided for direct blending. A standard 1/8 in. ID tube is provided for attaching an external oxygen source to the LSTAT Ventilator. This Tube is labeled "O2" and it is located on the Pneumatic Module.

WARNING: THE EXTERNAL O2 SOURCE MUST BE REGULATED TO AT LEAST 30 PSI AND NO GREATER THAN 60 PSI.

WARNING: USE CAUTION WHEN USING OXYGEN, IT IS EXTREMELY VOLATILE.

WARNING: ENSURE THE OXYGEN VALVE IS OFF WHEN NOT IN USE.

7.5 PRESSURE SENSE CONNECTIONS

Two 1/8 in. ID tubes are provided on the Pneumatic Module for pressure sensing. These two tubes connect to the Control Display module. The pressure sense tubes are color coded (blue and red) to insure correct connection to the Control Display module.

CAUTION: THE PRESSURE SENSE TUBES (BLUE AND RED) MUST BE CONNECTED CORRECTLY TO THE CONTROL DISPLAY MODULE. THE BLUE TUBE IS CONNECTED TO THE PNEUMATIC CONNECTION LABELED WITH THE BLUE DOT. LIKEWISE, THE RED TUBE MUST BE CONNECTED TO THE PNEUMATIC CONNECTION LABELED WITH THE RED DOT. INCORRECT CONNECTION OF THESE TUBES WILL DAMAGE THE VENTILATOR.

7.6 ELECTRIC CONNECTIONS

7.6.1 PRIMARY POWER

A 120 VAC power connection is required for the Control Display Module and a 120 VAC power connection is required for the Compressor Module. The 120 VAC power entry for the Control Display Module is located on the back panel. This power entry has a 1A Slo-Blo fuse in the fuse holder. The 120 VAC power entry for the Pneumatic Module is located on the front of the module. This power entry has a 10A Slo-Blo fuse. The power entry module connector is compatible with standard PH-386, IEC 320-C-13 connectors. Two power cords are provided, rated at 125V at 60° C, with NEMA 5-15P grounding plug. Connect the Ventilator power cords to grounded sockets only.

7.6.2 COM1, COM2, COM3 CABLES

Three 10 wire flat ribbon cables connect the sensors (FLOTRAK, EtCO₂, and SpO₂) located in the Pneumatic Module to the Control Processor located in the Control Display Module. The cable emanates from the right side of the Pneumatic Module and are individually labeled, COM1, COM2, and COM3. These three cables plug into correspondingly labeled connectors on the back panel of the Control Display Module. The plugs and connectors are keyed, so it is impossible to plug them in backward.

7.6.3 BLENDER CABLE

A 16 conductor flat cable emanates from the right side of the Pneumatic Module. This cable is labeled Blender and it plugs into the connector labeled Blender on the back of the Control Display Module. The plug and connector are keyed, so it is impossible to plug it in backward.

7.6.4 VALVE CABLE

A 36 conductor wire bundle cable is provided to connect the valve drive electronic signals from the Control Display Module to the Valves in the Pneumatic Module. This cable connects to keyed matching connectors on the back of the Control Display Module and on the right side of the Pneumatic Module. The plugs and connectors are keyed, so it is impossible to plug them in backward.

7.6.4 COMPRESSOR SPEED CONTROL CABLE

A 3 conductor cable and a 1 conductor cable emanate from the right side of the Pneumatic Module. Likewise, a matting 3 conductor cable and a 1 conductor cable emanate from the right side of the Compressor Module. The 3 conductor cable is labeled COMP. SPEED. Connect the two cables to their matching connectors. The connectors are keyed, so it is impossible to plug them in backward.

8. CARE AND MAINTENANCE

8.1 CLEANING

The LSTAT Ventilator Display, Control Panel and connections should be wiped with a nearly dry cloth containing hydrogen peroxide solution, Cidex, or warm water and a mild detergent. Do NOT use isopropyl alcohol or other solvents for cleaning. Be sure to wipe all solution residue off.

The patient circuit disposable and not intended to be reused. During prolonged use the circuit can be wiped with a nearly dry cloth moistened with a mild detergent.

NOTE: The Display and switches are sealed to prevent moisture from entering the inside of the unit. However, care should still be taken to insure that wipe cloths are nearly dry during cleaning to prevent buildup of residue in crevices and under the switches.

CAUTION: THE PNEUMATIC CONNECTIONS MUST BE COVERED DURING CLEANING.

The following is a list of cleaning agents that are OK to use:

1. Warm water
2. Hydrogen Peroxide solution
3. Cidex
4. Liquid soap
5. Windex
6. Formula 409
7. Fantastik
8. Coverage
9. T.B.Q.
10. Wex-cide

Wex-cide and T.B.Q. are disinfectants that meet OSHA requirements, are EPA approved, and will not harm the outside of the Ventilator. The disinfectants should be thoroughly wiped away after ten minutes.

CAUTION: DO NOT USE THE FOLLOWING CLEANING AGENTS:

1. Butyl Alcohol
2. Denatured Ethanol
3. Freon
4. Chlorine Bleach Solution
5. Isopropyl Alcohol
6. Trichloroethane, Trichloroethylene
7. Acetone
8. Vesphene II
9. Enviroquat
10. Staphene
11. Misty.

NOTE: During cleaning, the Ventilator, its connections and external sensors should be checked for unusual wear or possible damage. All external tubes and cables should be checked for cracking or fraying.

8.2 MAINTENANCE

Inspect the Ventilator before each use. Check for unusual wear or damage. Replace tubes that are cracked and cables that are frayed.

Before each use, inspect and replace, if necessary, the external gas inlet filter. Before each use, inspect and replace, if necessary, the air intake filter.

WARNING: VERIFY THE VENTILATOR FUNCTIONS AFTER INSPECTING AND REPLACING FILTERS.

8.3 REPAIR

Repair must be performed by qualified personnel at the service depot or the factory. Field repair is not possible.

Every six months or after 1,500 hours of operation, the Ventilator should have a complete functional verification and safety check. The safety check is performed by qualified personnel at the service depot or factory.

8.4 STORAGE

The Ventilator connectors must be covered with their protective caps during periods of storage.

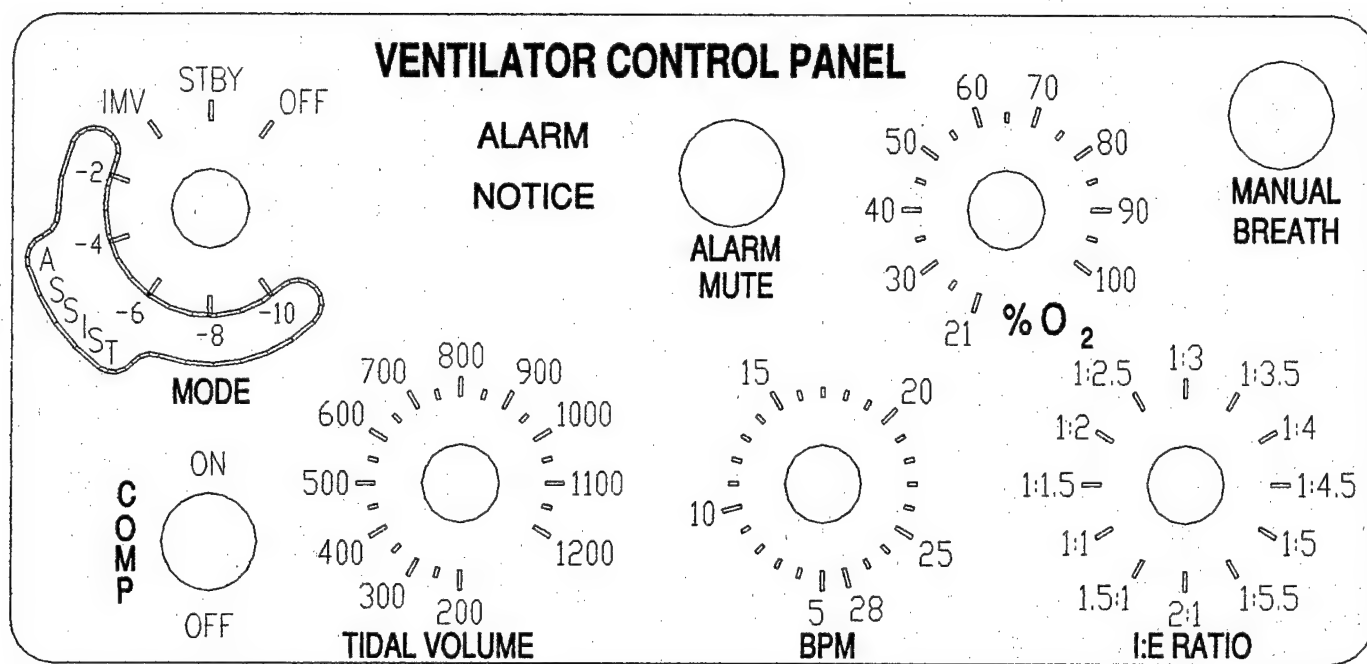
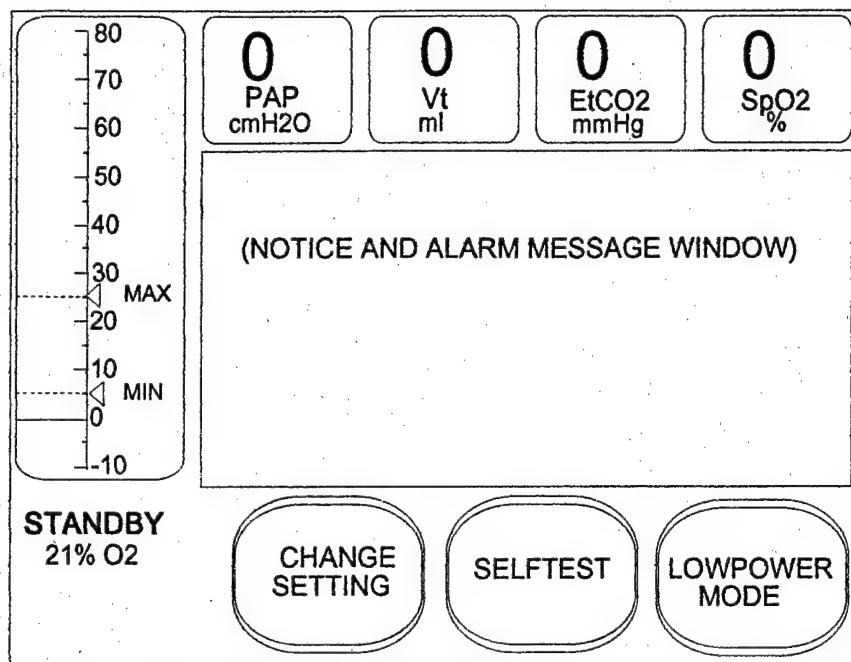
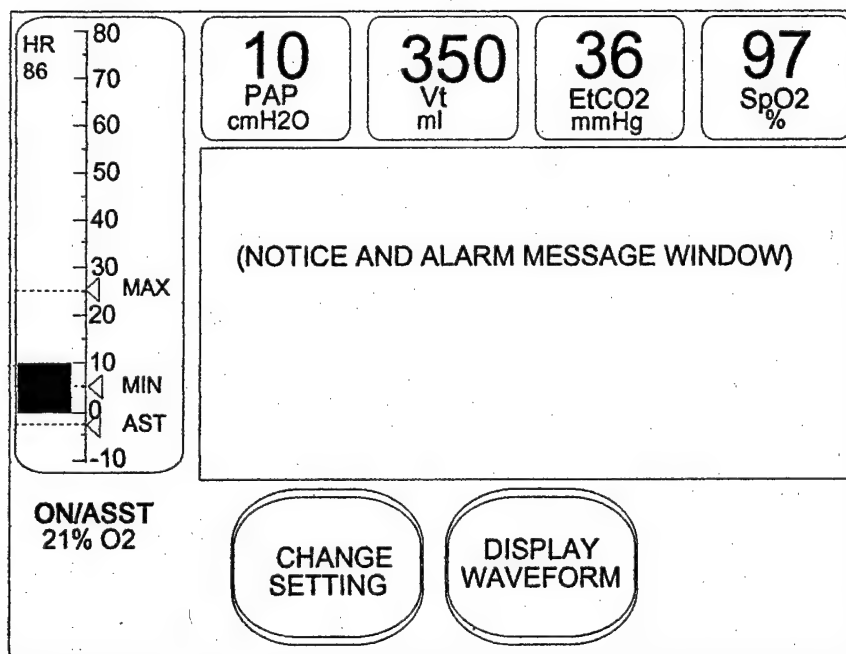


FIGURE 1. CONTROL PANEL



A. STANDBY



B. ON/ASST or ON/IMV

FIGURE 2. NORMAL(NO CHANGE OR WAVEFORM) SCREENS

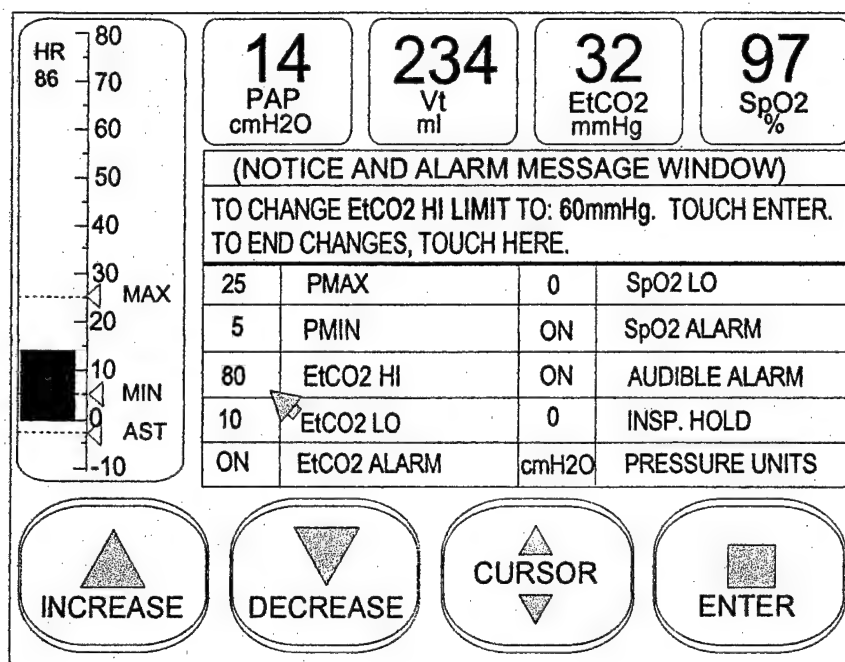


FIGURE 3a. CHANGE SCREEN 1

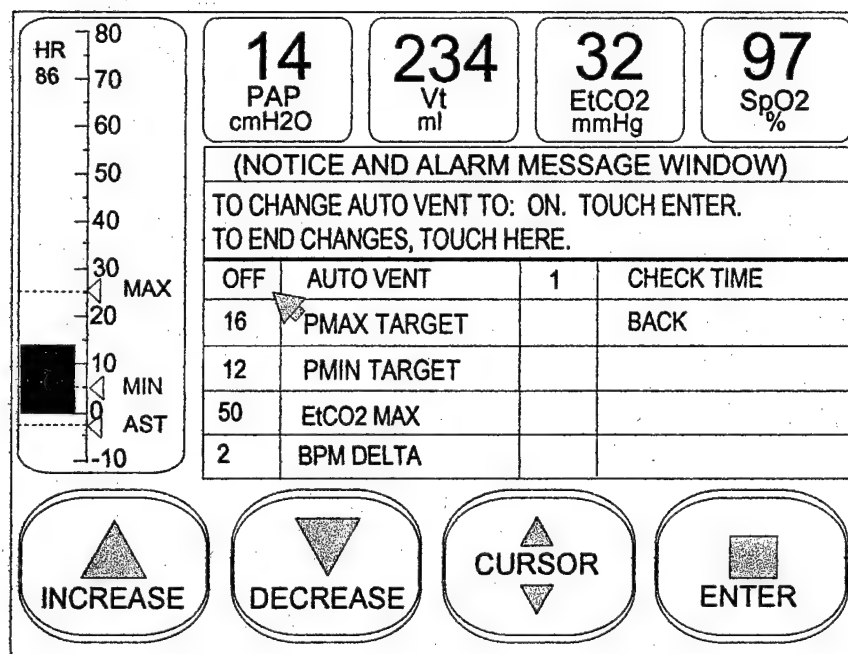


FIGURE 3b. CHANGE SCREEN 2

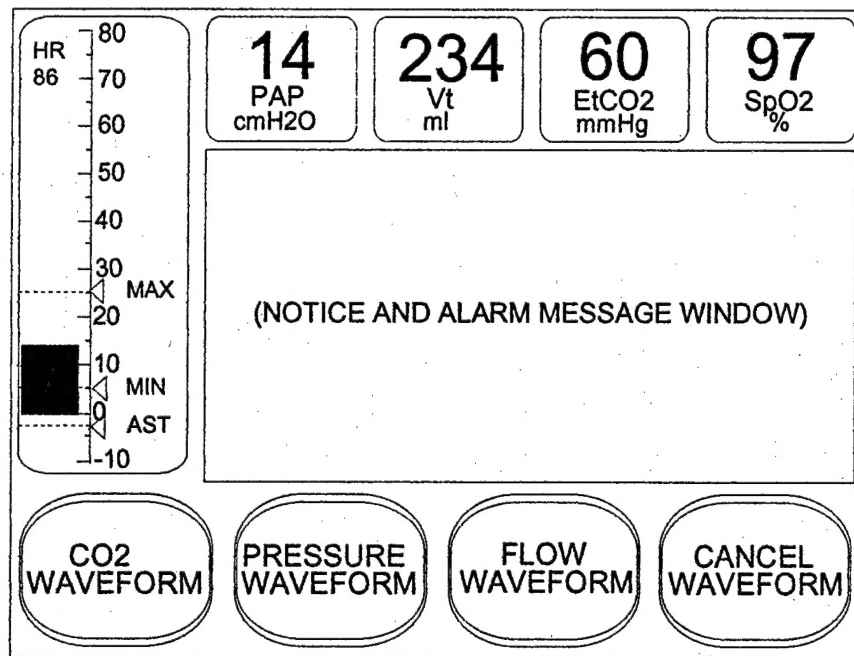


FIGURE 4. WAVEFORM SELECT SCREEN

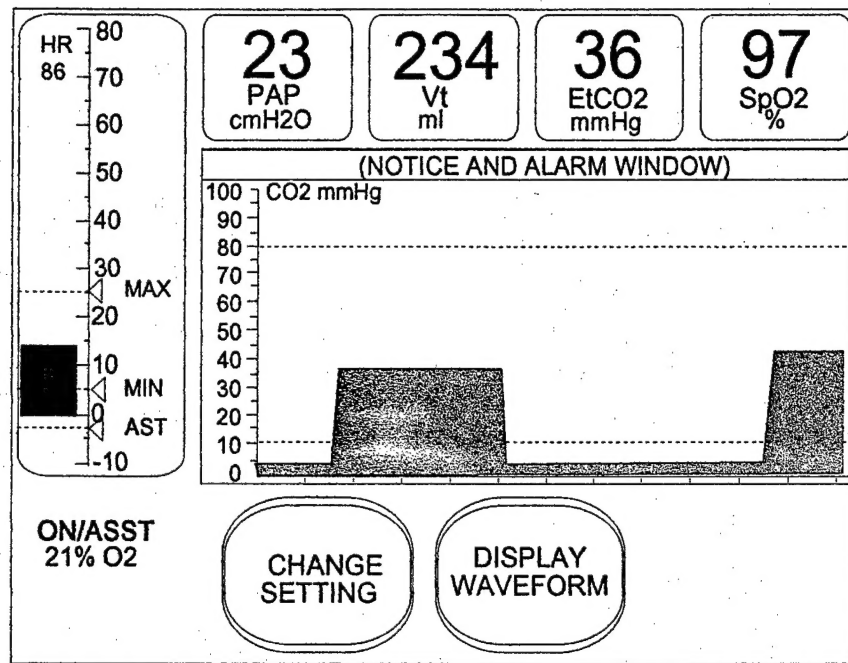


FIGURE 5a. CO2 WAVEFORM DISPLAY SCREEN

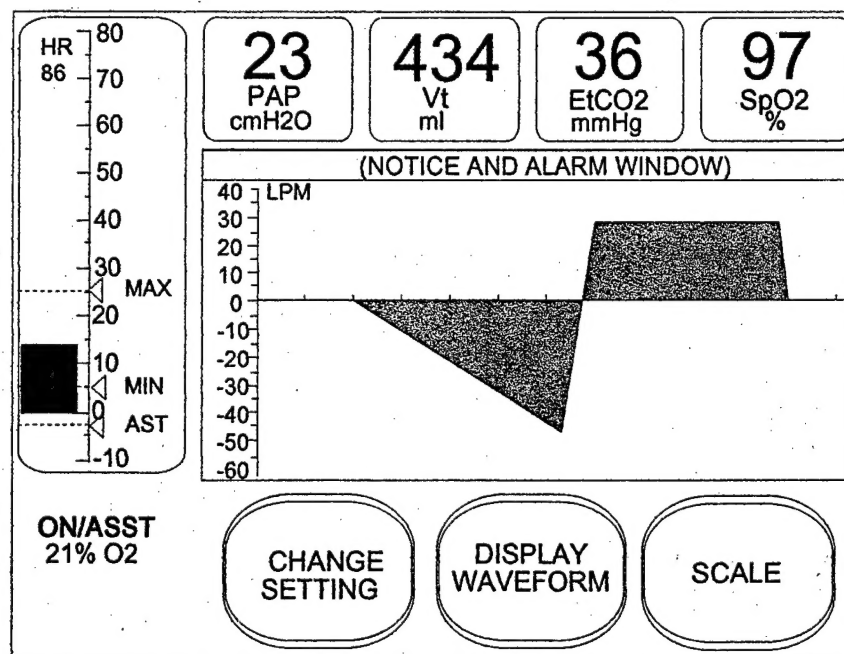


FIGURE 5b. FLOW WAVEFORM DISPLAY SCREEN

TOUCH HERE TO
CANCEL POWER SAVE MODE

FIGURE 6. LOWPOWER SCREEN

PRESSURE SENSE (RED, BLUE)

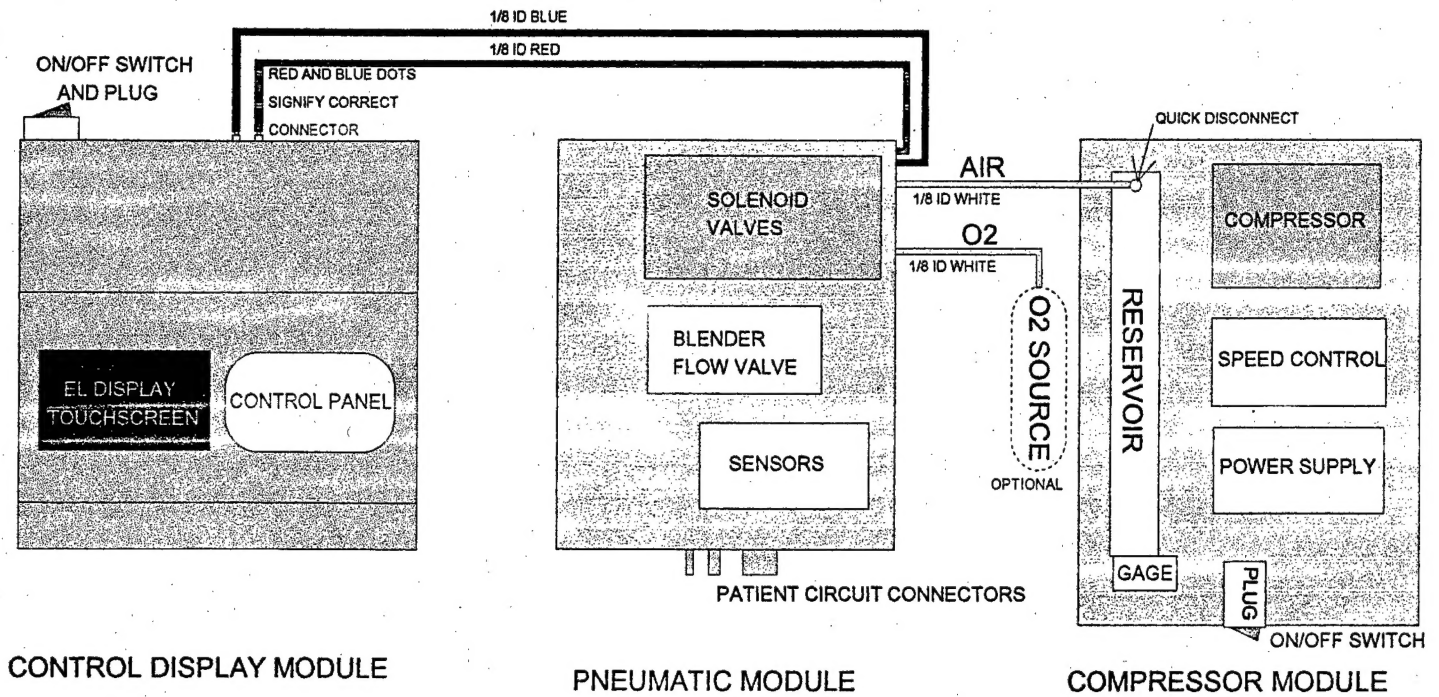


FIGURE 7a. PNEUMATIC CONNECTIONS (TOP VIEW)

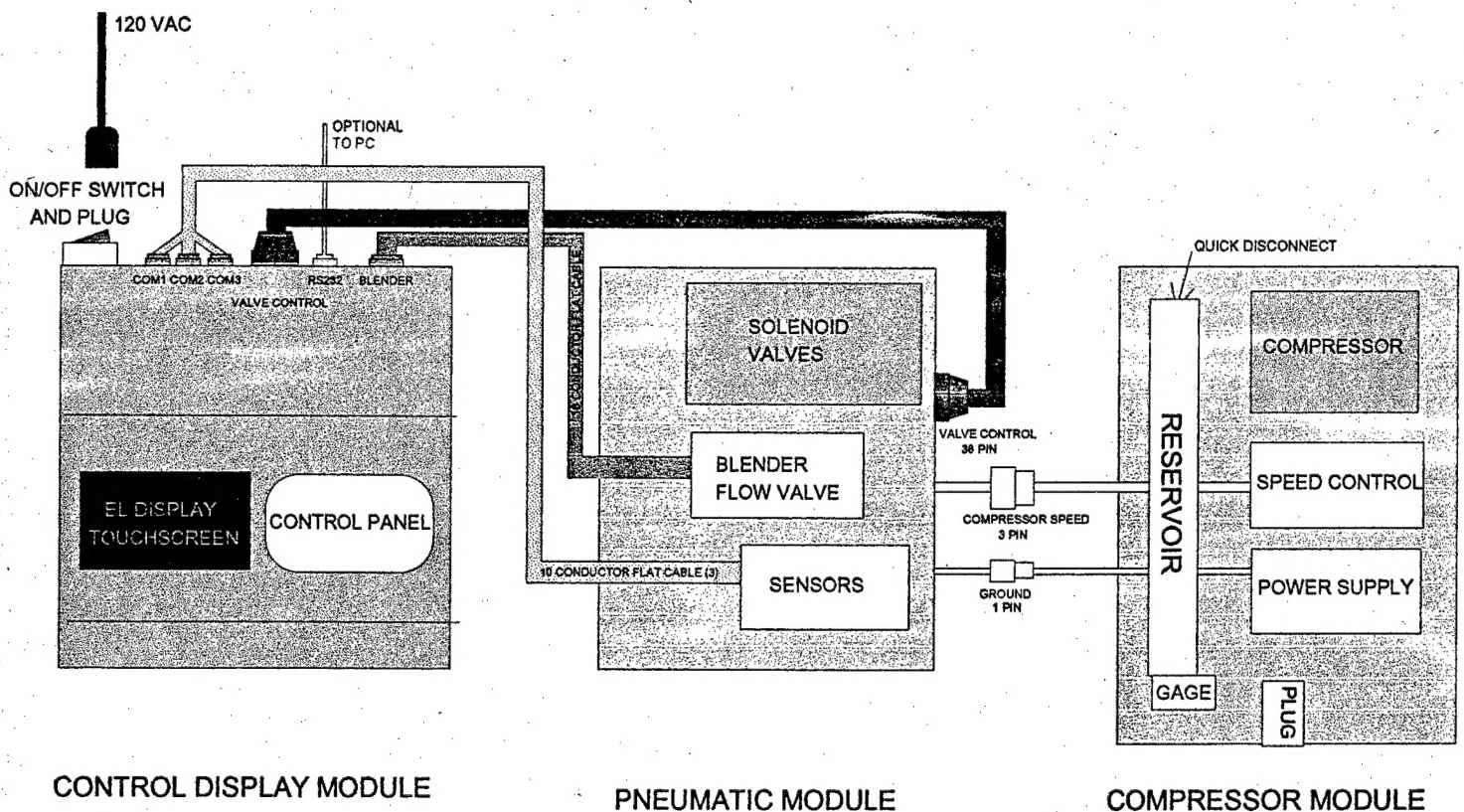


FIGURE 7b. ELECTRIC CONNECTIONS (TOP VIEW)